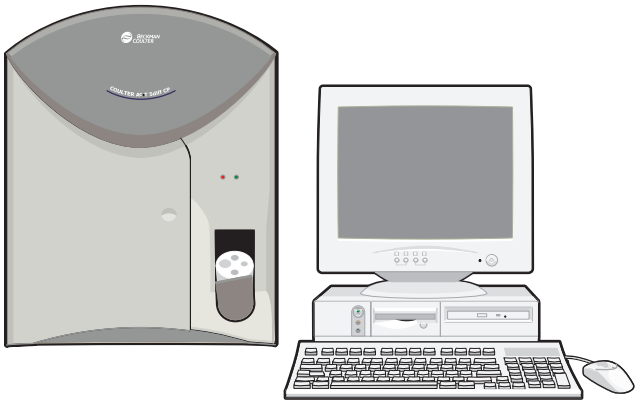
COULTER®
A^{C}•T™ 5diff Cap Pierce Hematology Analyzer

Instructions For Use



CE

PN 624021CA (June 2010)

Manufactured for
Beckman Coulter, Inc.
250 S. Kraemer Blvd.
Brea, CA 92821

BECKMAN COULTER

WARNINGS AND PRECAUTIONS

READ ALL PRODUCT MANUALS AND CONSULT WITH BECKMAN COULTER-TRAINED PERSONNEL BEFORE ATTEMPTING TO OPERATE INSTRUMENT. DO NOT ATTEMPT TO PERFORM ANY PROCEDURE BEFORE CAREFULLY READING ALL INSTRUCTIONS. ALWAYS FOLLOW PRODUCT LABELING AND MANUFACTURER'S RECOMMENDATIONS. IF IN DOUBT AS TO HOW TO PROCEED IN ANY SITUATION, CONTACT YOUR BECKMAN COULTER REPRESENTATIVE.

HAZARDS AND OPERATIONAL PRECAUTIONS AND LIMITATIONS

WARNINGS, CAUTIONS, and IMPORTANTS alert you as follows:

WARNING - Can cause injury.
CAUTION - Can cause damage to the instrument.
IMPORTANT - Can cause misleading results.

BECKMAN COULTER, INC. URGES ITS CUSTOMERS TO COMPLY WITH ALL NATIONAL HEALTH AND SAFETY STANDARDS SUCH AS THE USE OF BARRIER PROTECTION. THIS MAY INCLUDE, BUT IT IS NOT LIMITED TO, PROTECTIVE EYEWEAR, GLOVES, AND SUITABLE LABORATORY ATTIRE WHEN OPERATING OR MAINTAINING THIS OR ANY OTHER AUTOMATED LABORATORY ANALYZER.

WARNING Risk of operator injury if:

- All doors, covers and panels are not closed and secured in place prior to and during instrument operation.
- The integrity of safety interlocks and sensors is compromised.
- Instrument alarms and error messages are not acknowledged and acted upon.
- You contact moving parts.
- You mishandle broken parts.
- Doors, covers and panels are not opened, closed, removed and/or replaced with care.
- Improper tools are used for troubleshooting.

To avoid injury:

- Keep doors, covers and panels closed and secured in place while the instrument is in use.
- Take full advantage of the safety features of the instrument. Do not defeat safety interlocks and sensors.
- Acknowledge and act upon instrument alarms and error messages.
- Keep away from moving parts.
- Report any broken parts to your Beckman Coulter Representative.
- Open/remove and close/replace doors, covers and panels with care.
- Use the proper tools when troubleshooting.

CAUTION System integrity might be compromised and operational failures might occur if:

- This equipment is used in a manner other than specified. Operate the instrument as instructed in the Product Manuals.
- You introduce software that is not authorized by Beckman Coulter into your computer. Only operate your system's computer with software authorized by Beckman Coulter.
- You install software that is not an original copyrighted version. Only use software that is an original copyrighted version to prevent virus contamination.

IMPORTANT If you purchased this product from anyone other than Beckman Coulter or an authorized Beckman Coulter distributor, and, if it is not presently under a Beckman Coulter service maintenance agreement, Beckman Coulter cannot guarantee that the product is fitted with the most current mandatory engineering revisions or that you will receive the most current information bulletins concerning the product. If you purchased this product from a third party and would like further information concerning this topic, call your Beckman Coulter Representative.

REVISION STATUS

Issue A, 6/03
Software Version 1.0

Issue B, 10/04
Software Version 2.00.
Added procedure to clean baths and rinse block. Added information about the new features provided by software version 2.00. Updated illustrations.

Issue C, 02/05
Software Version 2.01.
Added IMPORTANT message in all appropriate places regarding the risk of failure to print and/or transmit all requested results if the delete function is used before printing and/or transmitting is complete.

Complies with the EU IVD Directive (98/79/EC).

Note: Changes that are part of the most recent revision are indicated in text by a bar in the margin of the amended page.

Issue CA, 06/10
Software Version 2.01.

Updates were made to the company corporate address.

Note: Changes that are part of the most recent revision are indicated in text by a bar in the margin of the amended page.

This document applies to the latest software listed and higher versions. When a subsequent software version changes the information in this document, a new issue will be released to the Beckman Coulter website. For labeling updates, go to www.beckmancoulter.com and download the most recent manual or system help for your instrument.

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OVERVIEW

This introductory section contains the following topics:

- USING YOUR A^{C}•T 5diff CP HEMATOLOGY ANALYZER OPERATOR'S GUIDE,
- ABOUT THIS MANUAL,
- CONVENTIONS,
- GRAPHICS, and
- SYMBOLS.

USING YOUR A^{C}•T 5diff CP HEMATOLOGY ANALYZER OPERATOR'S GUIDE

Use this Operator's Guide to find information about:

- getting started,
- running your instrument,
- reviewing results,
- performing special procedures, such as cleaning, replacing, or adjusting an instrument component,
- troubleshooting problems,
- determining what the instrument does,
- understanding how to safely operate the instrument,
- powering up the instrument,
- customizing the setup, and
- running controls and samples.

ABOUT THIS MANUAL

The information in this manual is organized as follows:

- Chapter 1, USE AND FUNCTION
  Contains the intended use of the instrument, a brief history of the methods used by the instrument, the reagents, calibrators, and controls used, a brief description of the major components, and how to work with the software.
- Chapter 2, OPERATION PRINCIPLES
  Contains the descriptions for cell counting and voting and how the parameters are derived.
- Chapter 3, SPECIFICATIONS/CHARACTERISTICS
  Details instrument specifications, characteristics, and interfering substances.
- Chapter 4, PRECAUTIONS/HAZARDS
  Provides information about key safety issues and contains information on biological hazards and hazards pertaining to moving parts.
- Chapter 5, GETTING STARTED
  Provides information on using the system's software and Workstation.

- Chapter 6, DAILY ROUTINE
  Provides information on doing daily procedures, such as Startup and Shutdown.
- Chapter 7, QUALITY ASSURANCE
  Provides information on how to run quality control material to verify calibration.
- Chapter 8, SAMPLE ANALYSIS
  Provides information on how to run patient blood samples.
- Chapter 9, DATA REVIEW
  Provides information on reviewing sample results, including flagged results
- Chapter 10, CALIBRATION
  Provides procedures for calibrating the instrument, including manually adjusting the calibration factors.
- Chapter 11, DIAGNOSTICS
  Provides information about special procedures and troubleshooting procedures for the instrument. Includes topics such as a maintenance schedule, cleaning and replacement procedures, and what error messages mean.
- Appendix A, SETUP
  Provides procedures on customizing the instrument's settings, such as date/time, reporting units, laboratory limits, and others.
- Appendix B, BARCODE SPECIFICATIONS
  Provides a procedure for testing, troubleshooting, and reprogramming the barcode scanner.
- Appendix C, MANUAL CALIBRATION
  Provides a procedure for manually calibrating the instrument.
- Appendix D, TUBE LIST
  Lists the tubes for use with the CP system.
- Appendix E, WORKSTATION MANAGEMENT
  Provides information about archive and database management.
- REFERENCES
  Lists references used in this manual.
- GLOSSARY
  Defines terminology used in this manual.
- ABBREVIATIONS
  Defines abbreviations used in this manual.
- INDEX
  Provides page numbers for indexed information.

CONVENTIONS

This manual uses the following conventions:

- Primary Window refers to the initial window displayed after you log on to the system software.
- When instructed to make a software selection, the text appears in bold with two symbols to distinguish the menu path. For example, if instructed to choose Startup from the Cycles menu, the text will appear as **CYCLES ▸▸ STARTUP.**
- **Bold font** indicates a software option, such as **CYCLES**.
- *Italics font* indicates screen text displayed on the instrument, such as *Calibration Passed*.
- ***Bold, italics font*** indicates a heading name within this document. For example, you may be instructed to do the Startup procedure, which would appear as "Do ***Startup***".
- Instrument refers to the A^{C}•T 5diff cap pierce hematology analyzer.
- CP refers to cap pierce.
- A **Note** contains supplemental information.
- An ATTENTION contains information that is important to remember or helpful when performing a procedure.
- Main card refers to the main circuit board (card) in the instrument.
- RBC bath is sometimes referred to as RBC/Plt bath.
- The terms "screen" and "window' are used interchangeably.
- A^{C}•T 5diff Rinse reagent is sometimes referred to as Rinse.
- A^{C}•T 5diff Fix reagent is sometimes referred to as Fix.
- A^{C}•T 5diff Hgb Lyse reagent is sometimes referred to as Hgb Lyse.
- A^{C}•T 5diff WBC Lyse reagent is sometimes referred to as WBC Lyse.
- A^{C}•T 5diff Diluent reagent is sometimes referred to as Diluent.
- indicates "select" with or "click" the mouse.

GRAPHICS

All graphics, including screens and printouts, are for illustration purposes only and must not be used for any other purpose.

SYMBOLS

Safety Symbols

Safety symbols alert you to potentially dangerous conditions. These symbols, together with text, apply to specific procedures and appear as needed throughout this manual.

Symbol	Warning Condition	Action
	Biohazard. Consider all materials (specimens, reagents, controls, and calibrators, and so forth) and areas these materials come into contact with as being potentially infectious.	Wear standard laboratory attire and follow safe laboratory procedures when handling any material in the laboratory.
	Probe hazard. The probe is sharp and may contain biohazardous materials, such as controls and calibrators.	Avoid any unnecessary contact with the probe and probe area.
	Electrical shock hazard. Possibility of electrical shock when instrument is plugged in to the power source.	Before continuing, unplug the A^{C}•T 5diff CP analyzer from the electrical outlet.

Tab Symbols

Tabs divide this document into five sections: reference, operation, special procedures and troubleshooting, appendices, and Workstation. Each tab reflects a unique symbol.

Symbol	Definition
	Identifies the reference section.
	Identifies the operating instructions section.
	Identifies the special procedures and troubleshooting section.
	Identifies the appendices section.
	Identifies the Workstation management section.

1.1 INTENDED USE

General

The COULTER A^{C}•T 5diff Cap Pierce (CP) hematology analyzer (Figure 1.1) is a 26-parameter, fully automated hematology analyzer, including a five-part leukocyte differential counter, capable of analyzing samples in a closed vial or open vial mode.

Of the 26 reported parameters:

- 20 parameters are **For In Vitro Diagnostic Use**: WBC, RBC, Hgb, Hct, MCV, MCH, MCHC, RDW, Plt, MPV, NE%, NE#, LY%, LY#, MO%, MO#, EO%, EO#, BA%, and BA#.
- 6 parameters are qualitative and are **For Research Use Only. Not for diagnostic procedures**.: Pct, PDW, IMM%, IMM#, ATL%, and ATL#.

Figure 1.1 A^{C}•T 5diff CP Analyzer

Purpose

The purpose of the A^{C}•T 5diff CP hematology analyzer is to identify normal patient results with all normal system-generated parameters and to flag or identify patient results that require additional studies.

1.2 DESCRIPTION

The instrument consists of the:

- A^{C}•T 5diff CP analyzer,
- Workstation (computer, monitor, keyboard, mouse, and software),
- barcode wand (optional),
- printer, and
- software kit.

IMPORTANT Risk of instrument damage and/or erroneous results if you install additional software onto the personal computer or if you use the personal computer for anything other than stated within this documentation.

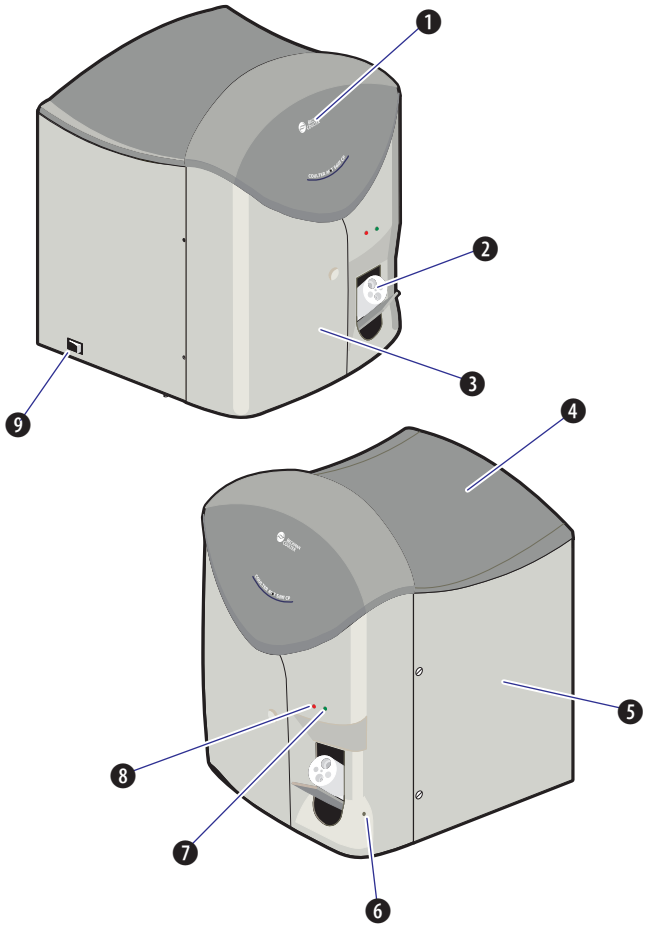
AC•T 5diff CP Analyzer

- Figure 1.2 shows an overview of the Analyzer.
- Figure 1.3 shows the back panel of the Analyzer.
- Figure 1.4 shows the warning and caution labels on the Analyzer.
- Figure 1.5 shows Tube Holder #1.
- Figure 1.6 shows Tube Holder #2.
- Figure 1.7 shows the position of tubes in the tube holders.

Overview of Instrument

WARNING Risk of operator injury when covers and doors are not closed and secured in place before you operate the instrument. Ensure that all covers and doors are closed and secured before operating the instrument.

Figure 1.2 Overview of Analyzer

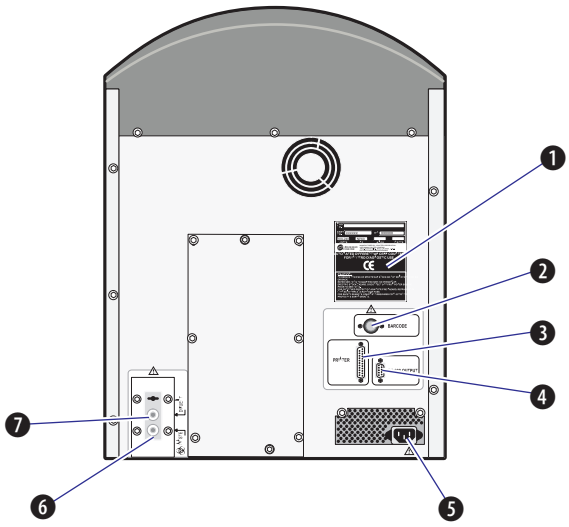


1. Front Cover
2. Tube Holder
3. Reagent Access Door
4. Top Cover
5. Right Side Door
6. Tube Holder Door – manual release
7. Green LED (indicates instrument is ready)
8. Red LED (indicates instrument is not ready)
9. Power ON/OFF switch

Back Panel

Figure 1.3 shows the Analyzer's back panel.

Figure 1.3 Analyzer: Back Panel

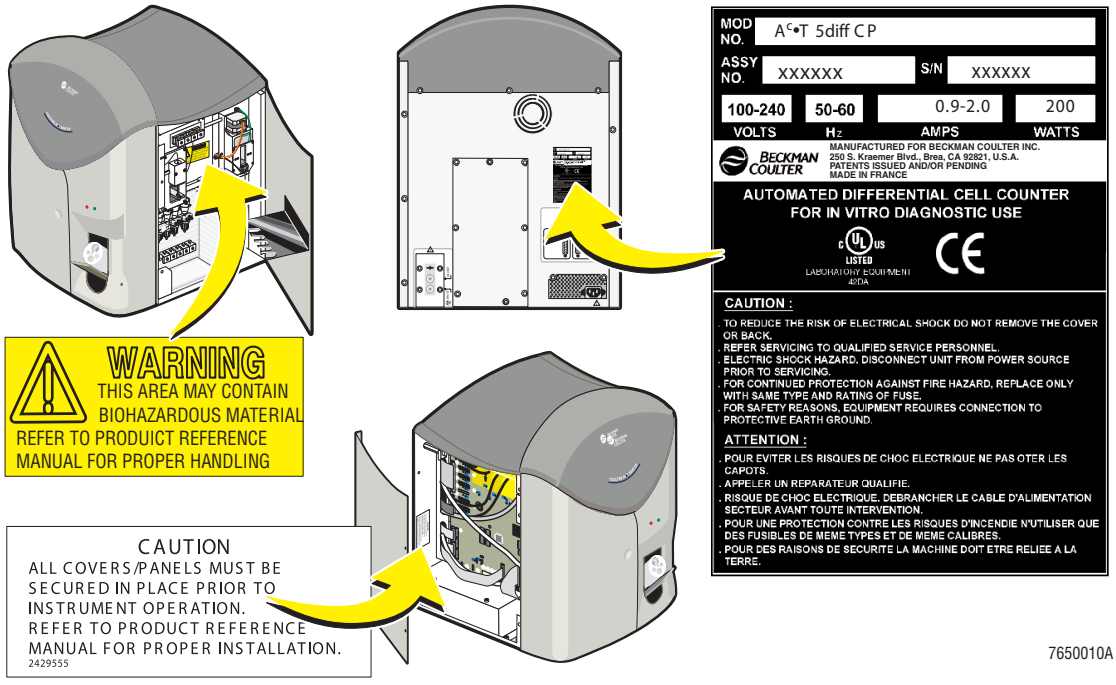


1. Serial number label
2. (Spare connector – not used)
3. (Spare connector – not used)
4. Workstation connector
5. Power supply cord connector
6. Waste output connector
7. Diluent input connector

Warning and Caution Labels

Pay close attention to the labels on the Analyzer (Figure 1.4). For warning and caution labels on the Workstation, refer to the manuals from the PC manufacturer for details.

Figure 1.4 Warning and Caution Labels: Analyzer

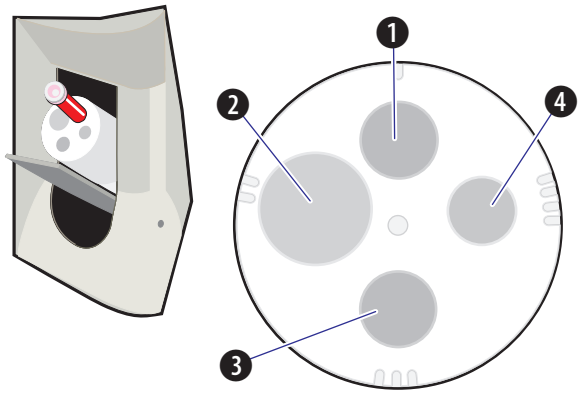

MOD NO. A^c•T 5diff CP
ASSY NO. XXXXXX
S/N XXXXXX
100-240 VOLTS
50-60 Hz
0.9-2.0 AMPS
200 WATTS
BECKMAN COULTER
MANUFACTURED FOR BECKMAN COULTER INC.
250 S. Kraemer Blvd., Brea, CA 92821, U.S.A.
PATENTS ISSUED AND/OR PENDING
MADE IN FRANCE
AUTOMATED DIFFERENTIAL CELL COUNTER
FOR IN VITRO DIAGNOSTIC USE
LISTED
LABORATORY EQUIPMENT
CAUTION :
. TO REDUCE THE RISK OF ELECTRICAL SHOCK DO NOT REMOVE THE COVER OR BACK.
. REFER SERVICING TO QUALIFIED SERVICE PERSONNEL.
. ELECTRIC SHOCK HAZARD. DISCONNECT UNIT FROM POWER SOURCE PRIOR TO SERVICING.
. FOR CONTINUED PROTECTION AGAINST FIRE HAZARD, REPLACE ONLY WITH SAME TYPE AND RATING OF FUSE.
. FOR SAFETY REASONS, EQUIPMENT REQUIRES CONNECTION TO PROTECTIVE EARTH GROUND.
ATTENTION :
. POUR EVITER LES RISQUES DE CHOC ELECTRIQUE NE PAS OTER LES CAPOTS.
. APPELER UN REPARATEUR QUALIFIE.
. RISQUE DE CHOC ELECTRIQUE. DEBRANCHER LE CABLE D'ALIMENTATION SECTEUR AVANT TOUTE INTERVENTION.
. POUR UNE PROTECTION CONTRE LES RISQUES D'INCENDIE N'UTILISER QUE DES FUSIBLES DE MEME TYPES ET DE MEME CALIBRES.
. POUR DES RAISONS DE SECURITE LA MACHINE DOIT ETRE RELIEE A LA TERRE.
WARNING
THIS AREA MAY CONTAIN BIOHAZARDOUS MATERIAL
REFER TO PRODUICT REFERENCE MANUAL FOR PROPER HANDLING
CAUTION
ALL COVERS/PANELS MUST BE SECURED IN PLACE PRIOR TO INSTRUMENT OPERATION.
REFER TO PRODUCT REFERENCE MANUAL FOR PROPER INSTALLATION.
2429555
7650010A

Tube Holders

Two interchangeable tube holders (Figures 1.5 and 1.6) are available for accommodating various size specimen tubes, microcollection devices, and control vials. Each tube holder contains four slots in which you can place an open or closed vial.

It is important to note that there is a single point of aspiration at the 12 o'clock position (referred to as the pierce position) on the Analyzer. To position the desired tube slot in the 12 o'clock pierce position, manually rotate the tube holder clockwise or counterclockwise as needed.

Figure 1.5 Tube Holder #1

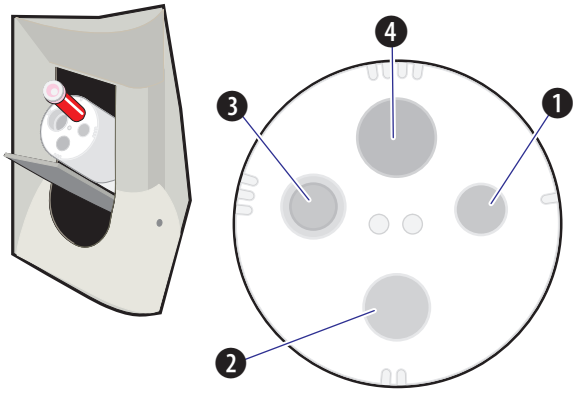


Slot Designations for Tube Holder #1

1. Position 1
2. Position 2
3. Position 3
4. Position 4

Note: Tube Holder #1 has one dot in the center.

Figure 1.6 Tube Holder #2



Slot Designations for Tube Holder #2

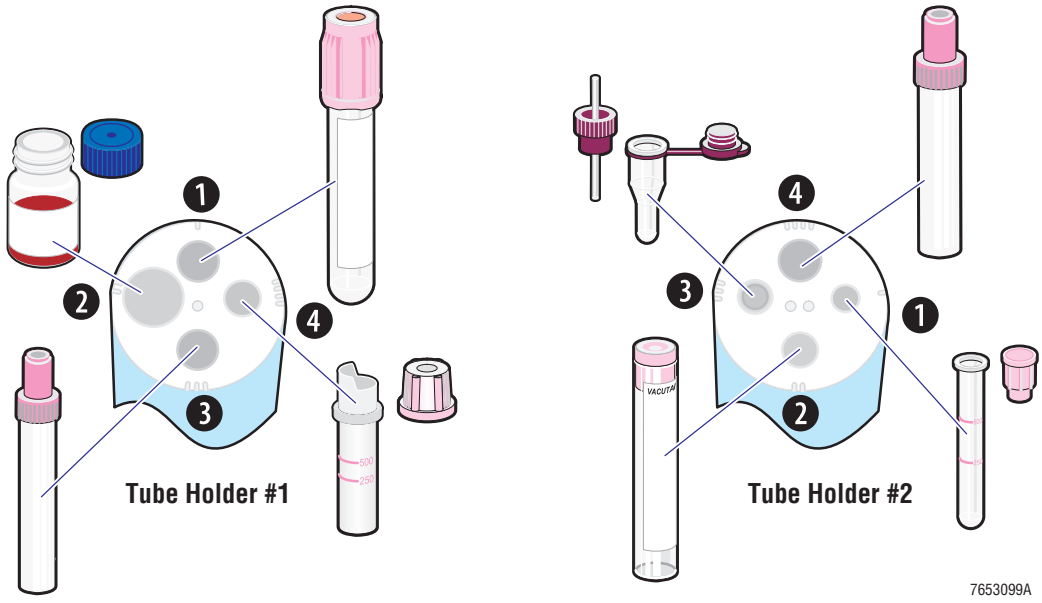
1. Position 1
2. Position 2
3. Position 3
4. Position 4

Note: Tube Holder #2 has two dots in the center.

As detailed in ***Appendix D, TUBE LIST***, each tube/vial has an assigned slot in a tube holder. Beckman Coulter does not guarantee the performance of any other tube on this system other than those listed in Appendix D.

Figure 1.7 shows examples of tubes in their correct slot and tube holder.

Figure 1.7 Tube Positions in the Tube Holders



The following list provides an **overview** of the tube holders and the tubes/vials they accommodate. For a detailed list, see ***Appendix D, TUBE LIST***.

Tube Holder #1 — **Types of Collection Devices or Control Vials**

Position ❶
- Most 13 mm x 75 mm evacuated specimen tubes containing either K_3EDTA or K_2EDTA for collecting whole-blood volumes of 2 to 5 mL
- COULTER® A^C•T™ 5diff Control Plus control tubes

Position ❷ COULTER® A^C•T™ 5diff Cal Calibrator vial

Position ❸ Sarstedt Monovette® 11.5 mm x 66 mm specimen tube collecting 2.7 mL of whole-blood

Position ❹ Becton-Dickinson Microtainer for collection of 0.25 to 0.50 mL of whole-blood

Tube Holder #2

Position ❶ Becton-Dickinson Microtainer for collection of 0.25 to 0.50 mL of whole-blood

Position ❷ Becton-Dickinson 10.25 mm x 64 mm Vacutainer® for collecting 3 mL of whole-blood

Position ❸ RAM Scientific microcollection device for collecting 125 µL of whole-blood

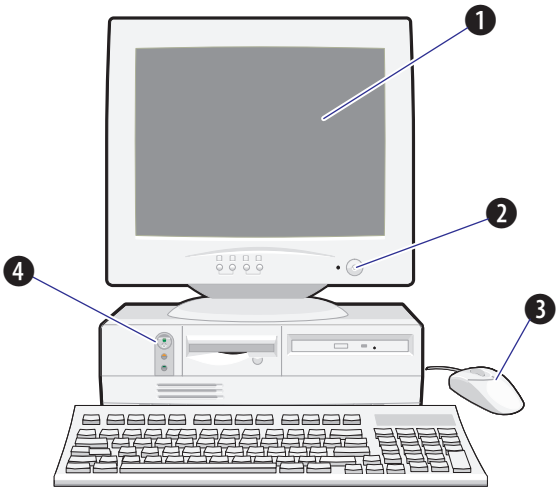
Position ❹ 13 mm x75 mm specimen tube with multiple labels

Workstation

Use the Workstation (Figure 1.8) to set up and operate the instrument.

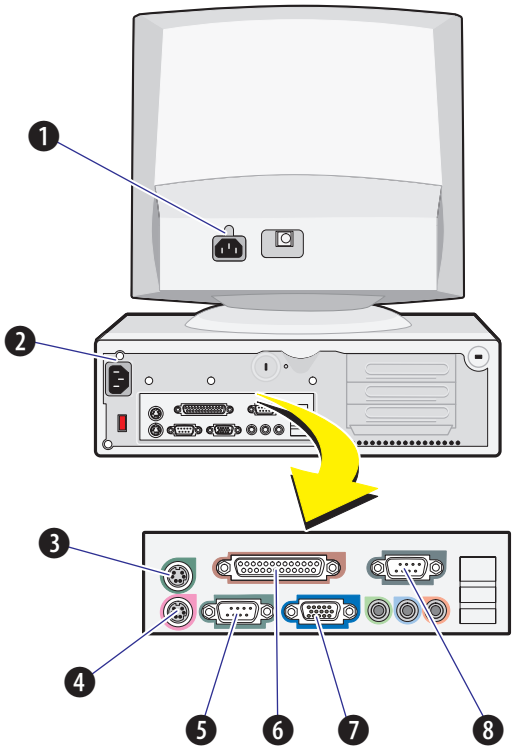
- Figure 1.8 shows the Workstation.
- Figure 1.9 shows the back of the Workstation.

Figure 1.8 Workstation



1. Monitor
2. Monitor power ON/OFF button
3. Mouse
4. PC power ON/OFF button

Figure 1.9 Back of Workstation



1. Power supply cord connector (monitor)
2. Power supply cord connector (PC)
3. Mouse connector
4. Keyboard connector
5. Analyzer connector
6. Printer connector
7. Monitor connector
8. Host communications connector

Note: Configurations may vary from what is shown here.

1.3 PANELS

You can run samples in either the CBC panel or CBC/DIFF panel. For information on the parameters of each panel, see ***Heading 1.4, PARAMETERS***.

1.4 PARAMETERS

CBC Panel

Table 1.1 lists the 12 parameters analyzed in the CBC panel.

Table 1.1 CBC Parameters

Parameter	Definition
WBC	White Blood Cell or leukocyte count
RBC	Red Blood Cell or erythrocyte count
Hgb	Hemoglobin concentration
Hct	Hematocrit (relative volume of erythrocytes within the whole-blood sample)
MCV	Mean Corpuscular (erythrocyte) Volume
MCH	Mean Corpuscular (erythrocyte) Hemoglobin
MCHC	Mean Corpuscular (erythrocyte) Hemoglobin Concentration
RDW	Red Cell (erythrocyte) Distribution Width
Plt	Platelet or thrombocyte count
MPV	Mean Platelet Volume
PDW†	Platelet Distribution Width
Pct†	Plateletcrit

†Pct and PDW are derived parameters and are For Research Use Only. Not for use in diagnostic procedures.

CBC/DIFF Panel

Table 1.2 lists the 26 parameters analyzed in the CBC/DIFF panel:

Table 1.2 CBC/DIFF Parameters

Parameter	Definition
WBC	White Blood Cell or leukocyte count NE%: Neutrophil percentage NE#: Neutrophil number, LY%: Lymphocyte percentage, LY#: Lymphocyte number, MO%: Monocyte percentage, MO#: Monocyte number EO%: Eosinophil percentage, EO#: Eosinophil number, BA%: Basophil percentage, BA#: Basophil number IMM%†: Immature cell percentage IMM#†: Immature cell number ATL%†: Atypical lymphocyte percentage ATL#†: Atypical lymphocyte number
RBC	Red Blood Cell or erythrocyte count
Hgb	Hemoglobin concentration
Hct	Hematocrit (relative volume of erythrocytes within the whole-blood sample)
MCV	Mean Corpuscular (erythrocyte) Volume
MCH	Mean Corpuscular (erythrocyte) Hemoglobin
MCHC	Mean Corpuscular (erythrocyte) Hemoglobin Concentration
RDW	Red Cell (erythrocyte) Distribution Width
Plt	Platelet or thrombocyte count
MPV	Mean Platelet (thrombocyte) Volume
PDW†	Platelet Distribution Width
Pct†	Plateletcrit

†Derived parameters are For Research Use Only. Not for use in diagnostic procedures.

1.5 FEATURES

Features of the instrument include automated calibration, automated quality control evaluation, automated patient data storage, closed vial sampling, aspiration with probe wipe, 12- or 26-parameter analysis with histograms and DiffPlots, and manually entered, autonumbered, or barcoded patient sample identification.

1.6 REPORTS

Sample result reports are printed based on your instrument setup. See ***Setting Up the Patient Report*** for details. For instructions on how to use the printer, refer to the printer's instruction manual.

In addition to sample reports, the instrument also generates other reports, such as:

- worklist reports,
- results list reports,
- control reports, including Levey-Jennings,
- reproducibility reports,
- calibration reports,
- XM reports, including Levey-Jennings, and
- log reports.

1.7 QUALITY ASSURANCE: CONTROLS, CALIBRATORS, AND IQAP

IQAP (Interlaboratory Quality Assurance Program)

Quality Assurance (QA) includes routine maintenance and service in conjunction with the use of controls and calibrators. The combination of these methods assures complete quality control and should be applied separately or in combination according to your laboratory, state, and federal protocols.

Participation in Beckman Coulter's IQAP helps you interpret control results and correlate them with your other internal quality control techniques. Your IQAP report will show how your laboratory performed in comparison with other laboratories.

For information on determining laboratory procedures, you can purchase the Physician's Office Laboratory Guideline (POL2-T) from the National Committee for Clinical Laboratory Standards (NCCLS) at 940 West Valley Road, Wayne, PA, 19087-1898, USA.

For additional information on IQAP, including how to enroll, contact your Beckman Coulter representative.

Cell Controls

A^{C}•T 5diff Control Plus is available in three levels (low, normal, and high) to provide a stable reference control for use with this instrument.

Refer to the control material package inserts for additional information, including stability for open and closed-vial use and for a list of measured parameters.

Calibrator

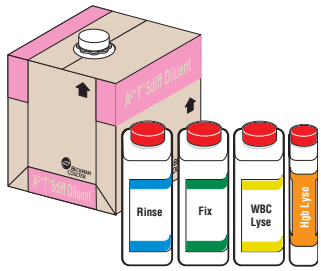
A^{C}•T 5diff Cal Calibrator is a recommended alternative to the whole-blood reference method of calibration and is traceable to reference methods and materials. Use A^{C}•T 5diff Cal Calibrator to ensure accurate instrument measurements for WBC, RBC, Plt, Hct, and Hgb.

1.8 REAGENTS

Recommended Reagents

Beckman Coulter recommends these reagents:

- A^{C}•T 5diff Diluent,
- A^{C}•T 5diff Fix,
- A^{C}•T 5diff WBC Lyse,
- A^{C}•T 5diff Hgb Lyse, and
- A^{C}•T 5diff Rinse.



These reagents are manufactured by Beckman Coulter Inc., Miami, Florida USA, and distributed by Beckman Coulter France, SA 33 rue des Vanesses BP 50359 Villepinte 95942 Roissy CDG Cedex.

All stated performance characteristics in this manual are based on the use of the instrument with the above-referenced reagents. Before using the reagent, refer to the reagent's bottle/container label for detailed information, such as stability.

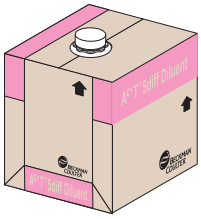
ATTENTION: The open container stability on the reagent labeling applies only to the reagent when connected to the instrument with approved reagent pickups and caps.

For information on handling reagent waste, see ***Waste Handling Procedures*** and ***Replacing the Waste Container***.

Reagent Descriptions

See Table 1.3.

Table 1.3 Reagent Descriptions

Reagent	Description
A^{C}•T **5diff Diluent** 	**WARNING** Risk of explosion if sodium azide is not properly flushed down the drain with large volumes of water. Sodium azide preservative may form explosive compounds in metal drain lines. (See National Institute for Occupational Safety and Health Bulletin: Explosive Azide Hazards [8/16/76].) When disposing of reagents down the drain, flush with large volumes of water. Used for counting and differentiating blood cells, A^{C}•T 5diff Diluent is clear and odorless. Composed of stabilized saline solution containing an organic buffer and less than 0.1% sodium azide, A^{C}•T 5diff Diluent: • Dilutes whole-blood samples, • Stabilizes cell membranes for accurate counting and sizing, • Conducts aperture current, and • Rinses instrument components between analyses. Handle as indicated in this manual. Use at ambient temperature from 18°C to 25°C up to the expiration date indicated on the packaging.
A^{C}•T **5diff Fix**	Used to lyse erythrocytes, fix leukocytes, and differentially stain granules of monocytes, neutrophils, and eosinophils, A^{C}•T 5diff Fix is a deep blue aqueous solution that smells like alcohol. A^{C}•T 5diff Fix is composed of an alcohol solution containing propylene-glycol, a formic dye, buffers, alkaline salts, wetting agents, and an aldehyde preservative. Handle as indicated in this manual. Use at ambient temperature from 18°C to 25°C up to the expiration date indicated on the packaging.
A^{C}•T **5diff WBC Lyse**	Used to lyse red blood cells for the leukocyte count and to differentiate poly-nuclear basophils, A^{C}•T 5diff WBC Lyse is a colorless, aqueous solution. It is composed of an acidic solution containing a lytic agent. Handle as indicated in this manual. Use at ambient temperature from 18°C to 25°C up to the expiration date indicated on the packaging.
A^{C}•T **5diff Hgb Lyse**	Used to lyse blood cells and to determine hemoglobin concentration, A^{C}•T 5diff Hgb Lyse is a clear, aqueous solution and is composed of potassium cyanide at 0.035, and a quarternary ammonium salt. Handle as indicated in this manual. Use at ambient temperature from 18°C to 25°C up to the expiration date indicated on the packaging.
A^{C}•T **5diff Rinse**	Used as a rinsing agent, A^{C}•T 5diff Rinse is a transparent liquid composed of an enzymatic solution with proteolytic action. Handle as indicated in this manual. Use at ambient temperature from 18°C to 25°C up to the expiration date indicated on the packaging.

Waste Handling Procedures

WARNING Risk of personal injury if waste is not neutralized before the waste container is capped. Non-neutralized waste contents may produce gas, which can build up pressure in a capped container. Neutralize waste contents after removing the waste container and before capping it for disposal.

Consult the material safety data sheets (MSDS) for additional reagent information. To order an MSDS, see ***Heading 1.10, ORDERING MATERIAL SAFETY DATA SHEETS (MSDS)***.

Neutralizing the Waste and Treating for Biohazards

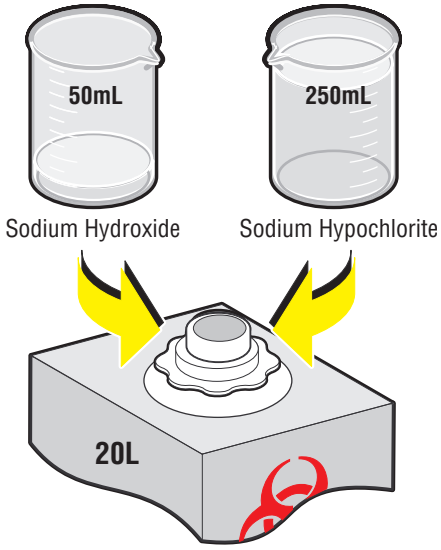
Do this procedure before capping the waste container for disposal.

WARNING Risk of personal injury if waste is not neutralized before the waste container is capped. Non-neutralized waste contents may produce gas, which can build up pressure in a capped container. Neutralize waste contents after removing the waste container and before capping it for disposal.

1 For 20L of waste liquid, add the following to the waste container:

a. 50mL of Sodium Hydroxide solution 200g/L to prevent gas from forming.

a. 250mL of Sodium Hypochlorite solution (12% available chlorine) to treat waste for biohazards.



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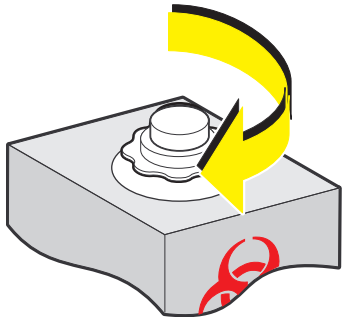
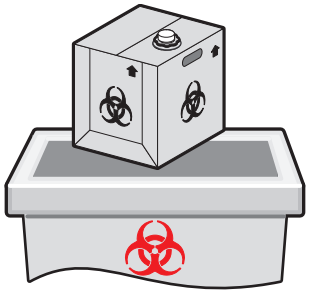
2 Cap the waste container and firmly tighten the cap to prevent waste contents from escaping.



3 Dispose of the waste container according to your laboratory's guidelines.



Handling Expired Reagents

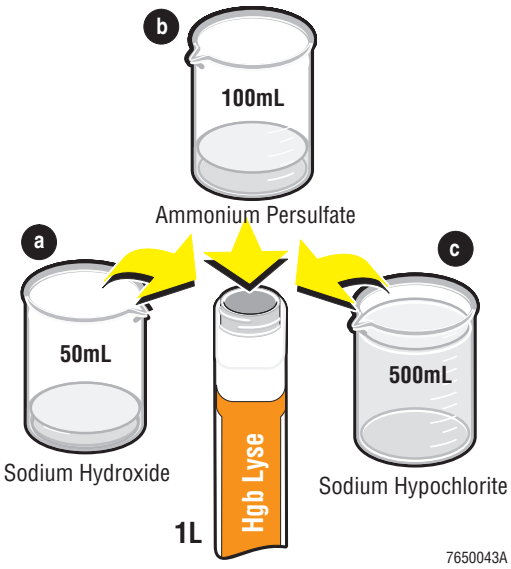
Do this procedure to eliminate cyanides from expired A^{C}•T 5diff Hgb Lyse.

1 For 1L of reagent, add:

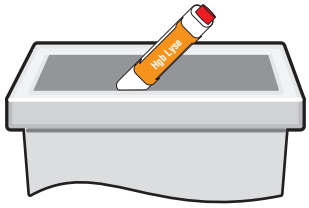
a. 50mL of Sodium Hydroxide solution 200g/L.

b. 100mL of freshly prepared Ammonium Persulfate solution 500g/L or 50mL of Sodium Hydroxide solution 500g/L.

c. 500mL of Sodium Hypochlorite solution (30% available chlorine).



2 Dispose of expired reagents according to your laboratory's guidelines.



1.9 PRINTER

Use the printer supplied or approved by Beckman Coulter.

1.10 ORDERING MATERIAL SAFETY DATA SHEETS (MSDS)

To obtain an MSDS for Beckman Coulter reagents used on the A^{C}•T 5diff CP analyzer:

1. On the Internet, go to *www.beckmancoulter.com*:
   a. Select MSDS from the Customer Support drop-down menu.
   b. Follow the instructions on the screen.
   c. Contact you Beckman Coulter representative if you have difficulty locating the information.
2. If you do not have Internet access:
   - In the USA, either call Beckman Coulter Customer Operations (800.526.7694) or write to:

     Beckman Coulter, Inc.
     Attn: MSDS Requests
     P.O. Box 169015
     Miami, FL 33116-9015
   - Outside the USA, contact a Beckman Coulter representative.

2.1 OVERVIEW

The A^{C}•T 5diff CP analyzer is a fully-automated hematology analyzer providing a complete WBC five-part differential, which is determined simultaneously by the A^{C}V (Absorbance Cytochemistry and Volume) Technology and WBC/BASO methodologies.

The A^{C}V Technology uses absorbance, cytochemistry, and focused flow impedance. The WBC/BASO methodology uses differential lysis, impedance technology, and differential thresholds. See Table 2.1.

Table 2.1 A^{C}•T 5diff CP Analyzer: Measurement Technologies

Fluid Dynamics	Technology	Measurements	Output
Dual Focused Flow	A^{C}V Technology	Light absorbance of cytochemically-stained cells	Lymphocytes, monocytes, neutrophils, eosinophils, immature cells, and atypical lymphocytes
Volume aperture	Differential lysis using the Coulter Principle	Volume and count	WBC count, basophil percentage, and basophil count
Volume aperture	Coulter Principle	Volume and count	RBC count, platelet count, and hematocrit

2.2 MEASUREMENT PRINCIPLES

Coulter Principle

In the A^{C}•T 5diff CP analyzer, the Coulter Principle[1] is used to analyze the final RBC/Plt dilution and the WBC/BASO dilution. This electronic method of counting and sizing particles is based on the fact that cells, which are poor conductors of electricity, will interrupt a current flow. The impedance variation generated by the passage of non-conductive cells through a small, calibrated aperture is used to determine the count (number of particles) and size (volume) of the particles passing through the aperture within a given time period.

Aperture Sensor System

Overview

The RBC/Plt aperture sensor system determines the cell count and size of red blood cells and platelets. The WBC/BASO aperture sensor system determines the cell count. The differentiation between basophils and other white blood cells is related to the A^{C}•T 5diff WBC Lyse-specific lytic action on the white blood cells in WBC/BASO bath.

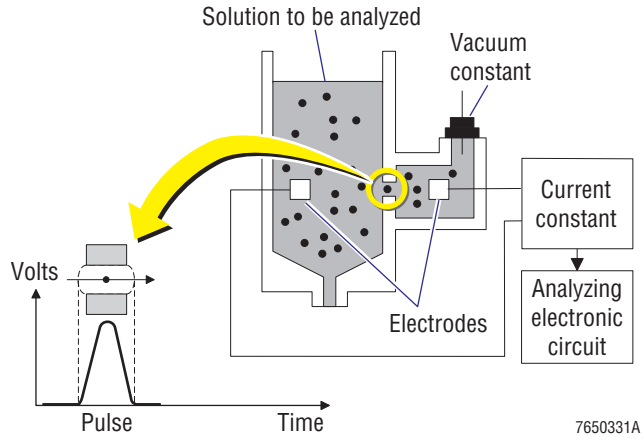
Particle Sensing

To sense particles using the Coulter Principle (Figure 2.1), a current flow is established so changes in that flow can be monitored. In this sensing system, an electrode is located on each side of the aperture.

The most visible electrode is referred to as the counting head. These electrodes are the conductive metallic housings attached to the front of the RBC and WBC/BASO baths. The

second electrode, referred to as the bath electrode, is not as noticeable; it is located inside the bath. The aperture is located between the counting head and the bath electrode.

Figure 2.1 Coulter Principle



When the count circuit is activated and an electronically conductive reagent is in the RBC or WBC/BASO bath, an electric current continuously passes through the aperture. Current moving between the two electrodes establishes the electronic flow through the aperture.

Once a sample is aspirated, an aliquot of that aspirated sample is diluted with reagent (an electrolyte) and is delivered to the RBC or WBC/BASO bath using tangential flow, which ensures proper mixing of the dilution. When the cells suspended in the conductive reagent are pulled through a calibrated aperture, the electrical resistance between the two electrodes increases proportionately with the cell volume (Figure 2.1).

The resistance creates a pulse that is sensed and counted as a particle by the instrument. The amount of resistance (amplitude of each pulse) is directly related to the size of the particle that produced it.

The generated pulses have a very low voltage, which the amplification circuit increases so that the electronic system can better analyze the pulses and eliminate the background noise.

Applying the Coulter Principle

The A^{C}•T 5diff CP analyzer makes several dilutions of an aspirated whole-blood sample. The RBC/Plt dilution begins in the First Dilution/Hgb bath but is actually analyzed in the RBC bath. The final dilution in the RBC bath is used to determine the cell count and size of red blood cells and platelets.

The WBC/BASO aperture sensor system is directly responsible for determining the cell count and size of white blood cells. The differentiation between basophils and other white blood cells is also related to the A^{C}•T 5diff WBC Lyse-specific lytic action on these white blood cells.

Thresholds, which are electronically set size limits, exclude unwanted particles, such as debris, from the analysis. Particles above the threshold are analyzed, and particles below the threshold are excluded.

2.3 A^CV TECHNOLOGY

Overview

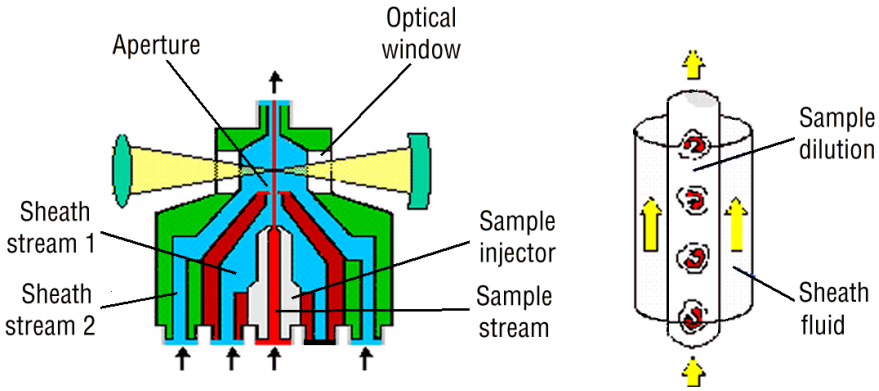
In the DIFF bath, 25 µL of whole blood is mixed with 1,000 µL of A^C•T 5diff Fix reagent for 12 seconds, then stabilized with 1,000 µL of A^C•T 5diff Diluent for an additional 3 seconds. This reaction lyses the red blood cells, preserves the leukocytes at their original size, and differentially stains the lymphocytes, monocytes, neutrophils, and eosinophils, with eosinophils staining most intensely. The instrument maintains the reagents and reaction at a regulated temperature of 35°C (95°F).

The lymphocytes, monocytes, neutrophils, and eosinophils each have a unique nuclear and morphologic structure and staining intensity; therefore, each absorbs light differently. Each stained cell is individually focused by the Dual Focused Flow (DFF) system and transported through the flow cell using sample pressure and diluent sheath flow.

Dual Focused Flow (DFF)

DFF (Figure 2.2) fluid dynamics uses a hydrodynamic focusing process to focus individual cells or particles in a stream of diluent. The focused sample stream of the A^C•T 5diff CP analyzer is about 40 µm in diameter.

Figure 2.2 Dual Focused Flow Process



DFF uses the sheath fluid to surround and force cells suspended in diluent to pass one at a time through the center of the flow cell. The first sheath flow focuses the sample through the impedance aperture. The second sheath flow maintains the focused flow of cells as they exit the aperture into the optical flow cell.

Hydrodynamic focusing in the flow cell enables accurate and rapid cell-by-cell measurements on a large number of individual cells.

Flow Cell

Sequential analyses for cell volume (impedance) and light absorbance are performed in the flow cell. A total of 72 µL of sample is injected through the flow cell for 15 seconds. The flow cell incorporates a 60 µm aperture for cellular volume analysis and a 42 µm measurement area for light absorbance.

Focused Flow Impedance

Focused flow impedance technology measures the electrical resistance of a cell as it passes through the aperture in the flow cell. The change in resistance is directly proportional to the volume of the cell.

Absorbance Cytochemistry

As a cell passes through the optical portion of the flow cell, light is scattered in all directions. A sensor detects only forward scattered light. The optical measurement is derived as a function of the amount of light lost due to diffraction and absorbance, as compared to full transmission when no cell is present.

The collected signals are converted into voltage pulses and are processed. The magnitude of the voltage pulses are proportional to the physical and chemical characteristics of the cells being analyzed. Light absorbance is related to cellular contents (granularity, nuclear content, and so forth) after cytochemical staining. These measurements provide the information for lymphocytes, monocytes, neutrophils, eosinophils, and their precursors.

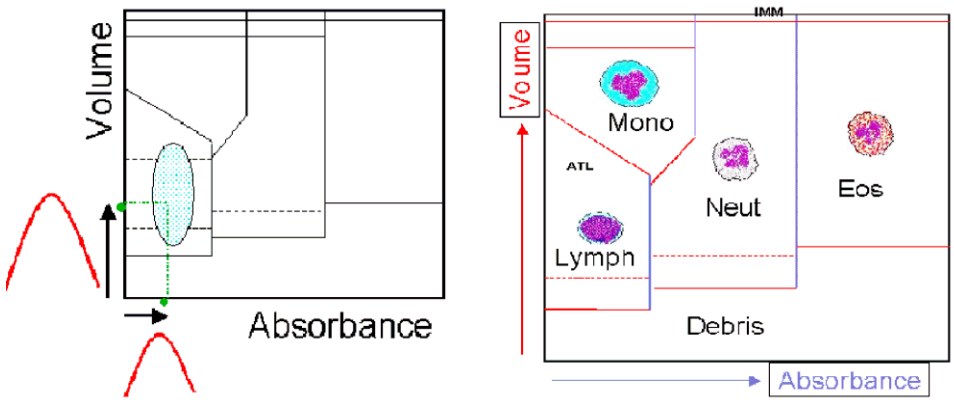
Signal Processing

Overview

The signals from the flow cell aperture and from the optical measurement are correlated by a window of time. The optical pulse must be detected within 100 to 300 microseconds of the impedance pulse, otherwise, the signal is rejected.

The output signals from the focused flow impedance and the light absorbance measurements are combined to define the WBC differential population clusters. See Figure 2.3.

Figure 2.3 Signal Processing



Thresholds

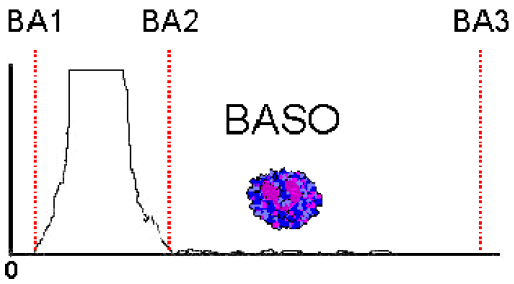
Most of the population partition thresholds are fixed and give the limits of the morphological normality of leukocytes. Changes in the morphology of a population are expressed on the DiffPlot by a shifting of the corresponding population. Volume and absorbance thresholds are used to detect shifting populations.

2.4 WBC/BASO METHODOLOGY

In the WBC/BASO bath, 10 µL of whole blood is mixed with 2,000 µL of A^{C}•T 5diff WBC Lyse reagent. This reaction lyses the red blood cells and specifically differentiates between the basophils and other leukocytes by volume. The instrument maintains the reagents and reaction at a regulated temperature of 35°C (95°F).

Using a constant vacuum, the instrument then pulls the sample through an 80 µm aperture. As each cell passes through the aperture, a pulse is generated proportional to the cellular volume. The total leukocyte count and basophil percentage are determined by specific thresholds on the WBC/BASO histogram (Figure 2.4.).

Figure 2.4 BASO Thresholds



2.5 SAMPLE ANALYSIS OVERVIEW

Aspiration

When the sampling probe is immersed in a whole-blood sample, the sample is pulled from the tube into the sampling probe. Depending on the selected panel of operation, the A^{C}•T 5diff CP analyzer aspirates either 30 µL (CBC panel) or 53 µL (CBC/DIFF panel) of sample.

The volume of sample aspirated into the sampling probe is sufficient to make all the dilutions needed to develop parameter results in the selected panel of operation. The aspirated sample is then partitioned as it is distributed into the designated baths.

Figure 2.5 shows the sample partitioning that occurs in the CBC/DIFF panel. Notice there are three aliquots of the aspirated whole-blood sample that will be used to make dilutions.

Figure 2.6 shows the sample partitioning that occurs in the CBC panel. Notice there are only two aliquots of the aspirated whole-blood sample that will be used to make dilutions in this panel of operation. (The DIFF aliquot is not needed in the CBC panel.)

To ensure sample integrity, the sample aliquot at the tip of the probe is never used to make a dilution; it is discarded into the Rinse bath.

Figure 2.5 Sample Partitions Inside the Probe - CBC/DIFF Panel

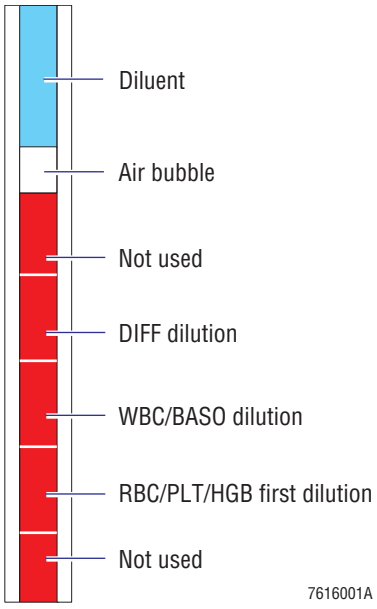
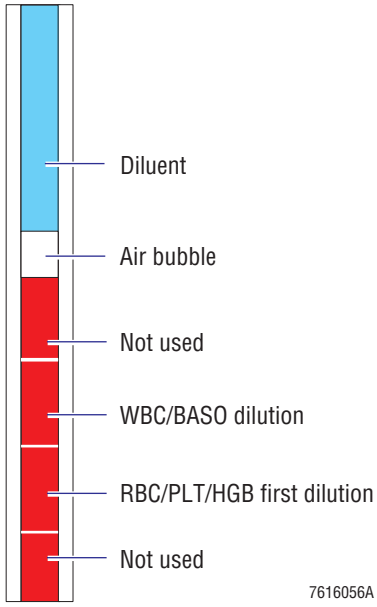


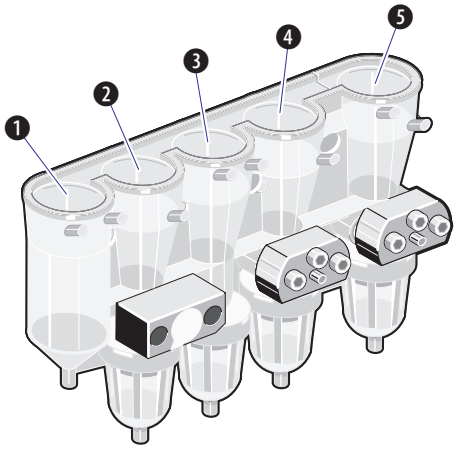
Figure 2.6 Sample Partitions Inside the Probe - CBC Panel



Dilution

Using the Sequential Dilution System (SDS) technique, the instrument makes a series of dilutions in a series of baths (Figure 2.7).

Figure 2.7 Bath Assembly



1. Rinse bath
2. First Dilution/Hgb bath
3. DIFF bath
4. RBC bath
5. WBC/BASO bath

CBC Panel

After aspiration in the CBC panel, aliquots of the whole-blood sample are distributed as follows (Figure 2.6):

- The 3 µL sample aliquot at the tip of the probe is discarded into the Rinse bath as the exterior of the sampling probe is rinsed, ensuring sample integrity.
- 10 µL of sample is delivered to the First Dilution/Hgb bath for use in preparing the primary RBC/Plt dilution and for measuring the Hgb value.
- 10 µL of sample is delivered to the WBC/BASO bath for the WBC/BASO count.
- 7 µL of remaining sample is discarded into the Rinse bath.

CBC/DIFF Panel

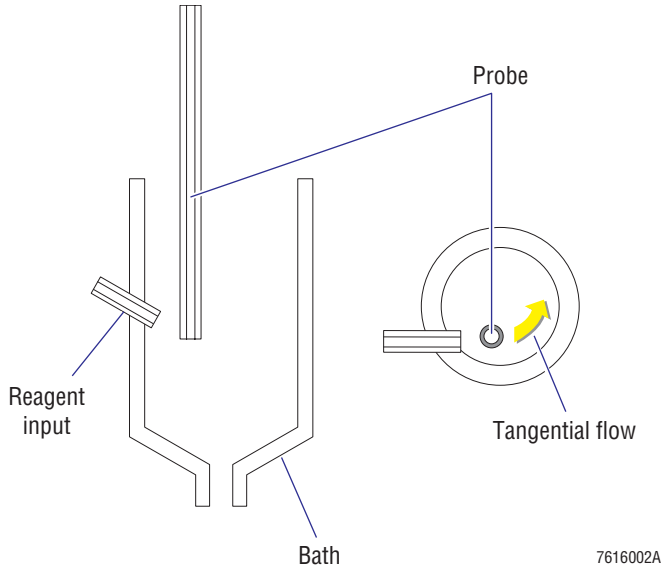
After aspiration in the CBC/DIFF panel, aliquots of the whole-blood sample are distributed as follows (Figure 2.5):

- The 3 µL sample aliquot at the tip of the probe is discarded into the Rinse bath as the exterior of the sampling probe is rinsed, ensuring sample integrity.
- 10 µL of sample is delivered to the First Dilution/Hgb bath for use in preparing the primary RBC/Plt dilution and for measuring the Hgb value.
- 10 µL of sample is delivered to the WBC/BASO bath for the WBC/BASO count.
- 25 µL of sample is delivered to the DIFF bath for development of the DiffPlot.
- 5 µL of remaining sample is discarded into the Rinse bath.

Delivery

In the CBC and the CBC/DIFF panels, each aliquotted sample is delivered to its appropriate bath using a tangential flow (Figure 2.8) of reagent. Tangential flow mixes the diluted sample and minimizes viscosity problems.

Figure 2.8 Sample Delivery Using Tangential Flow



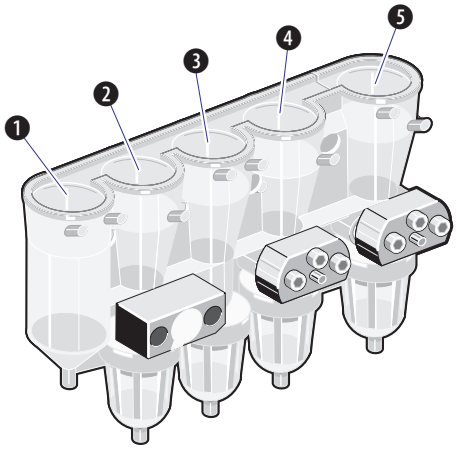
2.6 SAMPLE ANALYSIS

RBC and Platelet Analysis

The RBC/Plt dilution analyzes red blood cells and platelets. This dilution is prepared in two stages – the primary (first) dilution and the secondary (last) dilution.

The primary dilution is made in the First Dilution/Hgb bath, and the secondary dilution is made in the RBC bath (Figure 2.9). Table 2.2 summarizes the technical characteristics required to obtain RBC and Platelet results.

Figure 2.9 Bath Assembly



1. Rinse bath
2. First Dilution/Hgb bath
3. DIFF bath
4. RBC bath
5. WBC/BASO bath

Table 2.2 Technical Characteristics for Obtaining RBC and Platelet Counts

Dilution Characteristics	
Primary Dilution for RBC and Plt:	
Initial volume of whole-blood	10 µL
Volume A^{C}•T 5diff diluent	1,700 µL
Primary dilution ratio	1:170
Secondary Dilution for RBC and Plt:	
Volume of primary dilution	42.5 µL
Volume A^{C}•T 5diff diluent	2500 µL
Secondary dilution ratio	1:58.8
Final dilution for RBC and Plt results	1:170 x 1:58.8 = 1:10,000
Reaction temperature	35°C (95°F)
Measurement Characteristics	
Method of analysis	Coulter Principle
Aperture diameter	50 µm
Count vacuum	200mb (5.9in. Hg)
Count period	2x5 seconds

Parameter Results Obtained from the RBC/Plt Dilution

This final 1:10,000 RBC/Plt dilution is used to:

- Determine the RBC count,
- Develop the RBC histogram, which is needed to obtain the Hct, MCV, and RDW results,
- Determine Plt count,
- Develop the Plt histogram, which is needed to obtain MPV, Pct, and PDW results.

Hgb Measurement

Hemoglobin is determined from the dilution in the First Dilution/Hgb bath (Figure 2.9). This dilution is prepared in two stages – the primary (first) dilution and the secondary (last) dilution.

The primary dilution is made and 42.5 µL of that dilution is removed for making the RBC/Plt dilution. A^C•T 5diff Hgb Lyse and additional Diluent are added to make the final 1:250 dilution.

The Hgb concentration is based on the transmittance of light through the optical part of the First Dilution/Hgb bath using a spectrophotometric technique at a wavelength of 550nm. The transmittance of the sample dilution is compared to the transmittance of a reagent blank. The system calculates the Hgb using the blank and sample readings.

Table 2.3 summarizes the technical characteristics required for measuring hemoglobin.

Table 2.3 Technical Characteristics for the Measurement of the Hemoglobin

Dilution Characteristics	
Volume of whole-blood	10 µL
Volume A^C•T 5diff Diluent	1700 µL
Preliminary dilution ratio	1:170
Volume of the 1:170 dilution removed (for making the RBC/Plt dilution)	42.5 µL
Volume of A^C•T 5diff Hgb Lyse	400 µL
Additional volume of A^C•T 5diff Diluent	400 µL
Final dilution for Hgb determination	1:250
Reaction temperature	35°C (95°F)
Measurement Characteristics	
Method of analysis	Spectrophotometry
Wavelength	550nm

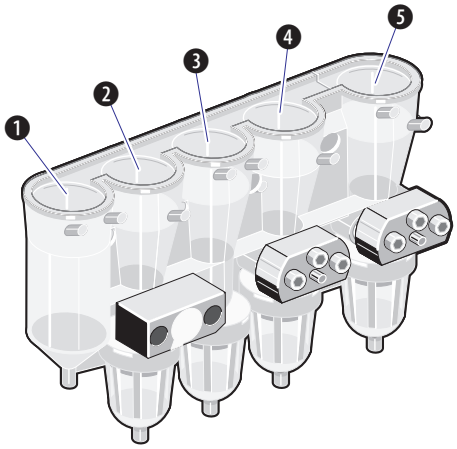
WBC Count and Differential

The WBC count is determined twice using two different methodologies:

- The reference WBC count is the count obtained in the WBC/BASO bath (Figure 2.10). The WBC count and the BASO count are determined simultaneously.
- A second WBC count is determined in the flow cell during acquisition of the DiffPlot. The dilution analyzed in the flow cell is prepared in the DIFF bath (Figure 2.10).

The WBC counts from the two methodologies are compared, and, if they exceed the defined limits, will be flagged.

Figure 2.10 Bath Assembly



1. Rinse bath
2. First Dilution/Hgb bath
3. DIFF bath
4. RBC bath
5. WBC/BASO bath

Table 2.4 summarizes the technical characteristics required to obtain WBC and BASO results.

Table 2.4 Characteristics Required to Obtain WBC/BASO Results

Dilution Characteristics	
Volume of whole-blood	10 µL
Volume A^{C}•T 5diff WBC Lyse	2,000 µL
Dilution ratio	1:200
Reaction temperature	35°C (95°F)
Measurement Characteristics	
Method of analysis	Coulter Principle
Aperture diameter	80 µm
Count vacuum	200 mb (5.9in. Hg)
Count period	2x6 seconds

Parameter Results Obtained from the WBC/BASO Dilution

The final 1:200 dilution is used to:

- Determine the WBC count, and
- Develop the WBC/BASO histogram, which is needed to obtain the BASO count.

Differential

Twenty-five microliters (25 µL) of whole blood are delivered to the DIFF bath in a flow of A^{C}•T 5diff Fix reagent, which:

- lyses the red blood cells,
- stabilizes the WBC in their native forms, and
- stains the lymphocytes, monocytes, neutrophils, and eosinophils differentially, with eosinophils staining most intensely.

The solution is then stabilized with Diluent for three seconds and transferred to the measuring bath. See Figure 2.11. Each cell is measured in absorbance (cytochemistry) and resistivity (volume).

Figure 2.11 Flow Cell Operation

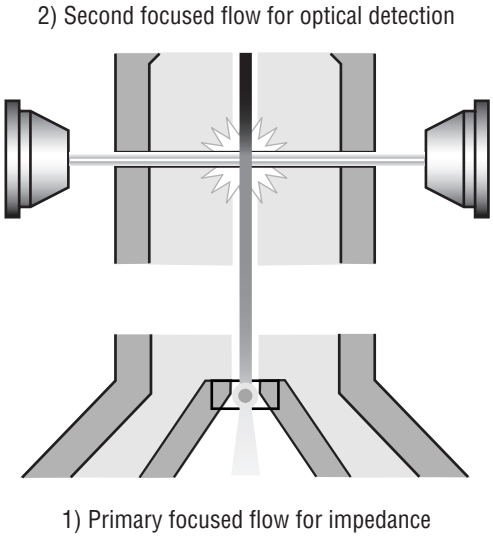


Table 2.5 summarizes the technical characteristics required for acquisition of the DiffPlot.

Table 2.5 Technical Characteristics for Acquisition of the DiffPlot

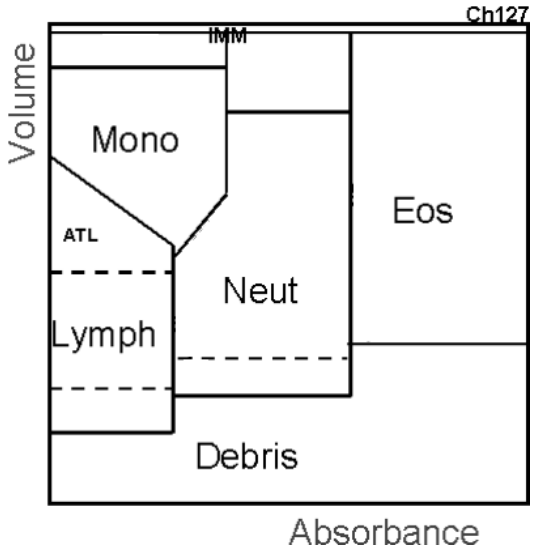
Dilution Characteristics	
Volume of whole-blood	25 µL
Volume A^{C}•T 5diff Fix	1,000 µL
Volume A^{C}•T 5diff Diluent	1,000 µL
Final dilution ratio	1:80
Reaction temperature	35°C (95°F)
Incubation duration	12 seconds
Measurement Characteristics	
Method of analysis	Impedance with hydrofocus
Aperture diameter	60 µm
Diameter of the flow	42 µm
Injection duration	15 seconds
Data accumulated	12 seconds
Volume injected	72 µL

Parameter Results Obtained from the DIFF Dilution

From the measurements described above, a DiffPlot is developed with optical transmission (absorbance) on the X-axis and volume on the Y-axis. Figure 2.12 shows the DiffPlot regions.

From the DiffPlot, four out of five leukocyte (white blood cell) populations are determined: lymphocytes, monocytes, neutrophils, and eosinophils. In a typical whole-blood sample, the basophil population (determined in the WBC/BASO bath) is very small compared to the other four white blood cell populations.

Figure 2.12 DiffPlot Regions



Dilution Summary

Table 2.6 summarizes the dilution characteristics required to obtain CBC and CBC/DIFF parameter results.

Table 2.6 Summary of Dilutions

Technical Characteristics	Whole-Blood Volume	Reagent(s)	Reagent Volume	Dilution Ratio	Reaction Temperature
WBC Count and BASO Count (in the WBC/BASO bath)	10 µL	A^{C}•T 5diff WBC Lyse	2,000 µL	Final 1:200	35°C (95°F)
Differential Acquisition with Differential WBC Count (in the DIFF bath)	25 µL	A^{C}•T 5diff Fix A^{C}•T 5diff Diluent	1,000 µL 1,000 µL	Final 1:80	35°C (95°F)
Hgb Measurement (in the First Dilution/Hgb bath)	10 µL	A^{C}•T 5diff Diluent After removing 42.5 µL of the 1:170 dilution: A^{C}•T 5diff Diluent A^{C}•T 5diff Hgb Lyse	1700 µL 400 µL 400 µL	Preliminary 1:170 Final 1:250	35°C (95°F)
RBC and Plt Count (in the RBC bath) **Note:** The primary dilution (1:170) is made in the First Dilution/Hgb bath.	42.5 µL of the 1:170 dilution (from the First Dilution/Hgb bath)	A^{C}•T 5diff Diluent	2,500 µL	Secondary 1:58.8 1:170 x 1:58.8 = Final 1:10,000	35°C (95°F)

2.7 PARAMETER DEVELOPMENT

RBC Parameters

Hct Measurement

Hct measurement: Hct (hematocrit) is the sum of all the digitized pulses. Hct is displayed and printed as % (percentage). (**Note**: % is the US unit format. Other formats are available. See ***Changing the Reporting Unit***.)

The height of the pulse generated by the passage of a cell through the aperture is directly proportional to the volume of the analyzed red blood cell.

RBC Count

The instrument uses duplicate counting criteria, voting criteria, and proprietary flagging information to confirm the parameter result prior to reporting it. To obtain an RBC count result, the instrument compares the data from the two 5-second count periods then votes and rejects any questionable data.

RBC count = Number of cells counted per unit volume x Calibration coefficient.

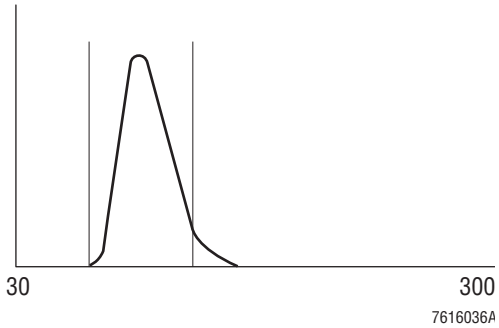
The RBC count is displayed and printed as: RBC = N x 10^6 cells/µL.
(**Note**: cells/µL is the US unit format. Other formats are available. See ***Changing the Reporting Unit***.)

RBC Histogram

In addition to being counted, red blood cells (RBCs) are categorized according to size (from 30 fL to 300 fL) by a 256-channel pulse-height analyzer. The pulse-height analyzer uses a number of thresholds to sort the particles into several size (volume) categories and to develop a size distribution curve of the particles.

The RBC distribution curve shows cells in their native size. Figure 2.13 is an example of an RBC histogram with a normal RBC size distribution.

Figure 2.13 Typical RBC Histogram



Parameter Results Obtained Using the RBC Histogram

- MCV calculation: MCV (Mean Cell Volume) is calculated using the Hct and the RBC count. The MCV is displayed and printed in femtoliters (fL). (**Note**: fL is the US unit format. Other formats are available. See ***Changing the Reporting Unit***.)
- RDW calculation: RDW (Red cell Distribution Width) is an index of the variation or spread in the size of the red blood cells. The study of the RBC distribution detects erythrocyte anomalies linked to anisocytosis and enables the clinician to follow the evolution of the width of the curve relative to the cell number and average volume. Displayed and printed as a percentage, RDW is calculated using the standard deviation (SD) of the RBC population and the MCV.

$$\text{RDW}(\%) = \frac{\text{K SD}}{\text{MCV}}$$

where:

K = System constant

SD = Calculated standard deviation based on the red cell distribution

MCV = Mean Cell Volume of the red cells

MCH and MCHC Calculations

- MCH calculation: MCH (Mean Cell Hemoglobin) is calculated from the Hgb value and the RBC count and describes the average weight of hemoglobin in a red cell. The calculation for MCH is:

$$\text{MCH (pg)} = \frac{\text{Hgb}}{\text{RBC}} \times 10$$

(**Note**: pg is the US unit format. Other formats are available. See ***Changing the Reporting Unit***.)

- MCHC calculation: MCHC (Mean Cell Hemoglobin Concentration) is calculated using the Hgb and Hct values and describes the average concentration of hemoglobin in the red blood cells. The calculation for MCHC is:

$$\text{MCHC (g/dL)} = \frac{\text{Hgb}}{\text{Hct}} \times 100$$

(**Note**: g/dL is the US unit format. Other formats are available. See ***Changing the Reporting Unit***.)

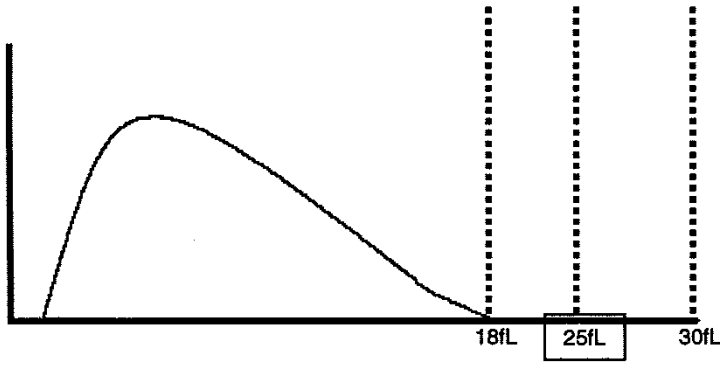
Plt Parameters

Overview

Platelet counting and sizing are also done in the RBC bath. Thresholds separate the platelet pulses, which are much smaller, from the red blood cell pulses. Platelets are also categorized according to size by a 256-channel pulse-height analyzer. A pulse-height analyzer uses a number of thresholds to sort the particles into several size (volume) categories and to develop a size distribution curve of the particles.

The Plt distribution curve shows cells in their native size. Figure 2.14 is an example of a Plt histogram with a normal Plt size distribution.

Figure 2.14 Typical Plt Histogram



Interference on the Lower End of the Platelet Distribution Curve

Particles that are approximately platelet size can interfere with the platelet histogram and count. Small particles, such as micro-bubbles, can interfere at the low end. If the number of pulses in the 2 to 3 fL region is higher than the predefined limits, an *SCL* flag appears to alert the operator that a significant number of small cells or interference, such as micro-bubbles, are present.

Microcytic Interferences on the Upper End of the Platelet Distribution Curve

Microcytic red blood cells can intrude at the upper end of the platelet distribution curve. If the sample contains microcytes, the instrument may be able to successfully eliminate the influence of this interference by repositioning the variable threshold and excluding the microcytes.

Parameter Results Obtained Using the Plt Histogram

- Plt Count: The instrument uses duplicate counting criteria, voting criteria, and proprietary flagging information to confirm the parameter result prior to reporting it. To obtain a Plt (platelet) count result, the instrument compares the data from the two 5-second count periods then votes and rejects any questionable data.

  Plt count = Number of cells counted per unit volume x Calibration coefficient.

  Plt count is displayed and printed as Plt = $Nx10^3$ cells/µL.
  (**Note**: cells/µL is the US unit format. Other formats are available. See ***Changing the Reporting Unit***.)

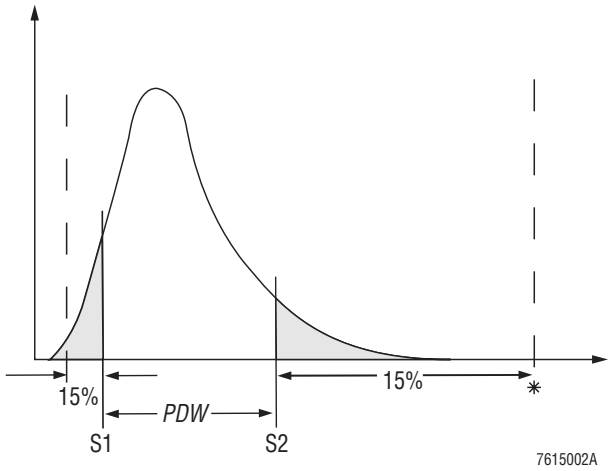
- MPV Measurement: MPV (Mean Platelet Volume) is measured directly from analysis of the platelet distribution curve. MPV is displayed and printed in femtoliters (fL).
- Pct Calculation: Pct (plateletcrit) is calculated according to the formula:

$$Pct\% = \frac{Plt\ (10^3/\mu L) \times MPV\ (fL)}{10,000}$$

- PDW Calculation: PDW (Platelet Distribution Width) is calculated from the Plt histogram as the width of the curve between S1 and S2.

  As shown in Figure 2.15, S1 and S2 are placed so that:
  - 15% of the platelets occur between 2fL and S1.
  - 15% of the platelets occur between S2 and the variable upper threshold.
  - The PDW result is determined on the platelets between S1 and S2.

Figure 2.15 Area of the Plt Histogram Used to Determine the PDW Parameter Result



Hgb Determination

The hemoglobin (Hgb) released by the lysis of the red blood cells combines with the potassium cyanide to form a stable cyanmethemoglobin compound.

This compound is measured through the optical part of the First Dilution/Hgb bath using a spectrophotometric technique at a wavelength of 550nm. Transmittance of the sample dilution is compared with the transmittance of a reagent blank. The system calculates the Hgb using both the blank and sample readings.

The final Hgb result represents: absorbance value obtained x coefficient of calibration.

Hgb is displayed and printed as Hgb = N g/dL.
(**Note**: g/dL is the US unit format. Other formats are available. See ***Changing the Reporting Unit***.)

WBC Count, BASO Count, and DiffPlot Development

WBC Count

The instrument uses duplicate counting criteria, voting criteria, and proprietary flagging information to confirm the parameter result prior to reporting it. To obtain an WBC (white blood cell) count result, the instrument compares the data from the two 5-second count periods then votes and rejects any questionable data. This is the reference WBC count, which is reported.

A second WBC count is determined in the flow cell during acquisition of the DiffPlot.

WBC count: Number of cells per volume x coefficient of calibration.

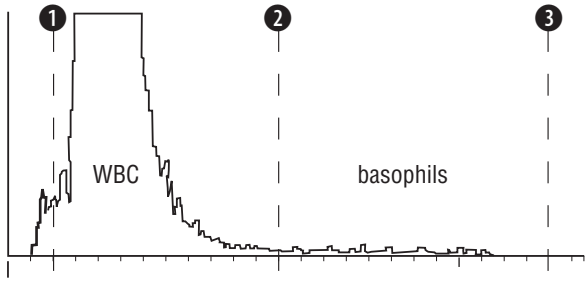
BASO Count

Differentiation between basophils and other leukocytes is obtained by means of the A^{C}•T 5diff WBC Lyse-specific lytic action.

In Figure 2.16, basophils are located in the area between the thresholds labeled ❷ and ❸. One hundred percent (100%) of the leukocytes is represented by the total number of nucleated particles plus the basophils within the area between the thresholds labeled ❶ and ❸.

The basophil percentage is calculated from the number of particles existing in the area between the thresholds labeled ❷ and ❸ (Figure 2.16).

Figure 2.16 Areas Used to Determine WBC and BASO Parameter Results



BASO count: Number of cells per volume x coefficient of calibration in percentage relative to the number of counted cells (BASO plus WBC nuclei).

$$\text{BASO count} = \frac{\text{BASO\%}}{\text{WBC\%}} \times \text{WBC count}$$

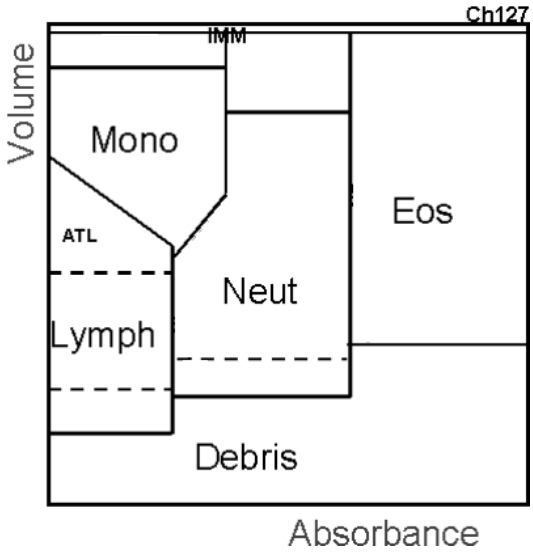
DiffPlot Development

The instrument's DiffPlot analysis is based on three essential principles:

1. Dual Focused Flow (DFF) fluid dynamics, which is a process by which individual cells or particles are focused in a stream of diluent (hydrodynamic focusing). For additional information, see ***Dual Focused Flow (DFF)*** in this chapter.
2. The volume measurement (Coulter Principle). For additional information, see ***Coulter Principle*** in this chapter.
3. The measurement of transmitted light with zero degree (0°) angle, which permits a response proportional to the internal structure of each cell and its absorbance. For additional information, see ***Absorbance Cytochemistry*** in this chapter.

From these measurements, a DiffPlot is developed with optical transmission (absorbance) on the X-axis and volume on the Y-axis. See Figure 2.17.

Figure 2.17 DiffPlot Regions



The study of the DiffPlot permits the clear differentiation of four out of five leukocyte populations. In a typical whole-blood sample, the basophil population is very small when compared with the other four white cell populations.

For additional DiffPlot information, see the following tables:

- Table 2.7 defines the DiffPlot regions.
- Table 2.8 defines immature white blood cells.

Table 2.7 DiffPlot Regions Defined

Region	Definition
Neutrophil (Neut)	Neutrophils, with their cytoplasmic granules and segmented nuclei, scatter light according to their morphological complexity. A hypersegmented neutrophil gives an increased optical response when compared to a young neutrophil population. The higher the complexity of the cell, the further to the right they appear in the DiffPlot (Figure 2.17).
Lymphocyte (Lymph)	Lymphocytes, typically being small with regular shape, are • smaller in volume and lower in absorbance than the other cells, and • positioned in the lower region of the DiffPlot (Figure 2.17). Normal lymphocyte populations typically have a homogeneous volume with a Gaussian (bell-shaped) distribution. Large lymphocytes, reactive lymphoid forms, stimulated lymphocytes, and plasma cells are found in the upper portion of the lymphocyte region (Figure 2.17). The lower area of the lymphocyte zone is normally empty; however, when small lymphocytes are present, a population may exist in this area (Figure 2.17). The presence of platelet aggregates is indicated by a distribution pattern that moves from the DiffPlot origin into the lymphocyte region (Figure 2.17). NRBC cytoplasmic membranes lyse like those of mature erythrocytes. The small nuclei that remain appear in the debris and small lymphocyte regions (Figure 2.17).
Monocyte (Mono)	Monocytes are typically large cells with a kidney-shaped nucleus and agranular cytoplasm. These cells neither scatter nor absorb large amounts of light; therefore, they are positioned in the lower end of the absorbance axis. Due to their size, the monocytes are clearly positioned high on the volume axis (Figure 2.17). Very large monocytes may be found in the IMM (immature cell) region.
Eosinophil (Eos)	With the reagent action, eosinophils are the most intensely stained for optical separation. Due to the staining intensity and their size, eosinophils show higher absorbance than the neutrophils, but they will be of similar volume (Figure 2.17).
Debris	Platelets and debris from erythrocyte lysis represent the background debris population located in the lower region of the DiffPlot.

Table 2.8 Immature White Blood Cells

Immature Cell Type	Definition
Immature Granulocytes	Immature granulocytes are detected by their larger volume and by the presence of granules that increase the intensity of the scattered light. Due to their increased volume and similar absorbance, promyelocytes, myelocytes, and metamyelocytes are located above the neutrophil population and are typically counted as IMM cells. IMM cells are included in the reported neutrophil value. See Figure 2.17.
Band Cells	Band cells are typically larger or of similar size to the neutrophils; however, due to their low level of cellular complexity, they absorb less light. As a result, band cells tend to appear in the region between the neutrophils and the monocytes.
Blast Cells	Blast cells are generally larger than monocytes and have similar absorbance. When blast cells are present, they are generally located above the monocytes, which means they will be included in the IMM cell count. Small blasts will be located between the normal lymphocyte and monocyte populations.

2.8 WORKLISTS

Definition

A Worklist is a list of samples to be processed. The Worklist also includes the patient information (demographics) that you enter – such as name, age, date of birth, gender, location, physician, and comments – for each Sample ID. If you want to add demographic information for a patient, you must do so before the sample is analyzed. The information that you enter is printed on the final report and transmitted to a host computer, if available.
Note: You cannot modify demographics received from a host computer.

For Worklist setup information, see ***Heading 5.13, USING WORKLISTS***.

Function

The Worklist has two functions – choosing a flagging set and storing patient demographics.

Duplicate Sample ID Check

The database maintains records of all Sample IDs processed. If an operator enters a Sample ID that has already been used but not yet archived, a *Duplicate Sample ID* warning message will appear.

If your laboratory Sample ID sequence repeats, it is necessary to clear the current memory of used numbers by archiving them. See ***Creating an Archive*** in Appendix E.

Creating a new archive resets the duplicate Sample ID process so that the IDs can be reused. How often you create a new archive depends on the frequency that your laboratory repeats sample IDs. Table 2.9 shows some worklist examples for repeating Sample IDs.

Table 2.9 Worklist Examples and Archive Frequency

How Often Sample IDs are Repeated	Example	When to Archive
Daily	Your laboratory starts the Sample ID numbering at “001” each day and continues the number sequence through the day, then restarts at “001” the next day.	At the beginning of each day, the previous days data has to be archived and a new archive created. See ***Creating an Archive***.
Monthly	Your laboratory starts the Sample ID numbering at “001” on the 1st day of each month and numbers sequentially through the month and then restarts at “001” the beginning of the next month.	At the start of each month, the previous month’s data has to be archived and a new archive created. See ***Creating an Archive***.
Annually	Your laboratory starts the Sample ID numbering at “001” on January 1 every year and numbers sequentially through the year and then restarts at “001” the beginning of the next year.	At the start of each year, the previous year’s data has to be archived and a new worklist created. See ***Creating an Archive***. Beckman Coulter recommends that you archive monthly since small archives are easier to navigate through and easier to manage than large ones

If your laboratory does not repeat the sequence of sample IDs – meaning that the sample IDs are always unique – archiving is not required. However, for practical purposes it is recommended that you archive monthly. Small archives are easier to navigate through and easier to manage than large ones.

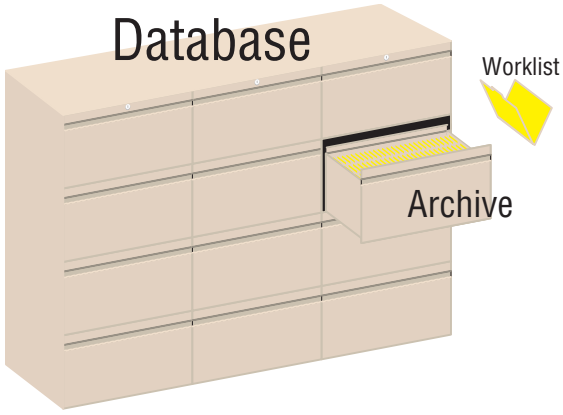
Demographics Storage

The Worklist allows you to add patient information, such as patient name, age, date of birth, gender, and so forth. This information is included with in the sample results. If information pertaining to age and or gender is added, the system automatically selects the appropriate flagging range. For additional information on flagging ranges, see ***Heading 9.3, REVIEWING FLAGGED RESULTS***. If the Patient ID is added, the information is stored relative to that Patient ID. The entered information can be retrieved by entering the Patient ID.

Database, Archive, and Worklist Relationships

On this system, the database is the larger electronic storage "cabinet" on the Workstation's hard drive. Within the database, the archive is a "file cabinet" and the worklist is a "folder" within the file cabinet. See Figure 2.18.

Figure 2.18 Database, Archive, and Worklist Relationships



The worklist and the results are linked together in their operation and should be considered as a single component within the database. This means that when you close an archive, the worklist information and results for all processed samples are archived at the same time. **The date of the archive is the date it was created.**

When an archive is opened, all samples analyzed will be listed on the worklist, including reproducibility, blanks, controls, and calibrators. Pending Worklist entries in an archive are displayed against a white background. Worklist entries with results are displayed against a green background. **Sample analysis is not permitted in an archive other than the current active archive**.

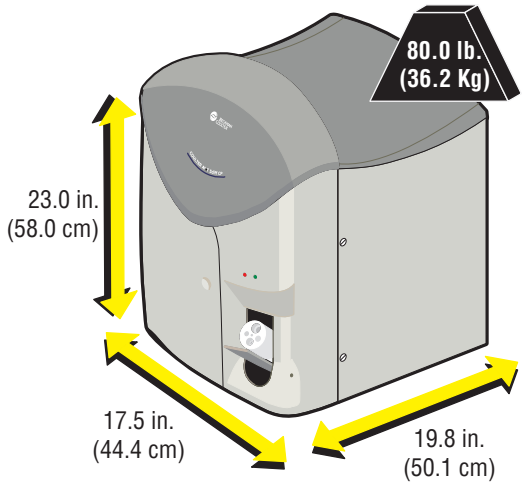
3.1 INSTRUMENT SPECIFICATIONS

Dimensions and Weight

See Figure 3.1.

WARNING Risk of operator injury if only one person lifts the instrument. The instrument has no lifting handles, and it weighs more than one person should lift. Therefore, to prevent injury, at least two people – following appropriate safety precautions – should lift the instrument together.

Figure 3.1 Analyzer Dimensions and Weight



For the dimensions and weight of the Workstation, refer to the PC, printer, and monitor documentation from the respective manufacturers.

Power

Supply

- From 100 Vac to 240 Vac (excluding the printer, which is voltage specific, e.g. 100 to 120 Vac or 220 to 240 Vac).
- From 50 Hz to 60 Hz.

Consumption

Maximum of 800 VA (for the Analyzer, Workstation, and printer).

Installation Category

The instrument is designed to be safe for transient voltages according to Installation Category II and Pollution Degree 2.

Grounding Requirements

To protect against electrical shock, the wall ground (earth) plug must be correctly connected to the laboratory grounding electricity installation.

Temperature, Ambient Operating

The ambient operating temperature is 16°C to 34°C (61°F to 93°F).

Altitude Range

The instrument can be operated at any altitude up to 3,000 meters (9,800 feet).

Recommended Location

Place the instrument indoors on a clean, level bench or workstation. Allow at least 20cm (8 in.) of space behind the instrument and the Workstation for ventilation. Do not expose the instrument or the Workstation to sunlight.

Electromagnetic Environment Check

The instrument is designed to produce less than the acceptable level of electromagnetic interference when properly placed. Electromagnetic interferences are limited to levels that allow the correct operation of other instruments conforming to their placement.

If there is a problem, ensure that the instrument is not placed near electromagnetic fields or short wave emissions (such as radar, X-ray machines, scanners, and so forth).

Recommended Reagents

Beckman Coulter recommends these reagents:

- A^{C}•T 5diff Diluent,
- A^{C}•T 5diff Fix,
- A^{C}•T 5diff WBC Lyse,
- A^{C}•T 5diff Hgb Lyse, and
- A^{C}•T 5diff Rinse.

See ***Heading 1.8, REAGENTS*** for additional information about these reagents.

Recommended Controls

A^{C}•T 5diff Control Plus is the recommended control. See ***Heading 1.7, QUALITY ASSURANCE: CONTROLS, CALIBRATORS, AND IQAP*** for additional information.

Recommended Calibrator

A^{C}•T 5diff Cal Calibrator is the recommended calibrator. See ***Heading 1.7, QUALITY ASSURANCE: CONTROLS, CALIBRATORS, AND IQAP*** for additional information.

Recommended Anticoagulant

The recommended anticoagulant is K_3EDTA, with the proper proportion of blood to anticoagulant as specified by the tube manufacturer. K_2EDTA is an acceptable alternative.

Sample Volume Aspirated

- 30 µL of whole blood is aspirated in the CBC mode.
- 53 µL of whole blood is aspirated in the CBC/DIFF mode.

Slightly higher volumes may be used depending on such variables as tube fill volume, sample viscosity and the amount of pressure/vacuum in the tube.

Dilution Ratios

WBC/BASO:	1/200
DIFF:	1/80
RBC/Plt:	1/10,000
Hgb:	1/250

Throughput

The instrument can process up to 60 samples per hour in either mode – CBC or CBC/DIFF.

The instrument achieves nominal throughput when used in a routine laboratory environment with samples having normal hematology parameters. Depending on sample mix and workflow conditions, slightly higher or lower throughput might be observed.

Sample Identification

You can manually enter a sample ID, setup the instrument to autonumber the IDs, or scan the tube's barcode label with the optional hand-held barcode reader.

Database Storage

The system can store up to 10,000 files.

Flagging Sets

The system can accommodate 20 flagging sets:

- 6 are predefined,
- 14 can be added.

Output

The instrument can transmit sample data to a host computer. The Sample Results screen shows the sample identification information, sample results, and any result flags.

The instrument prints a report (Figure 3.2).

Figure 3.2 Sample Report (Report Format Option 1)

YOUR LABORATORY NAME
CITY, STATE ZIP

YOUR LABORATORY ADDRESS 1
LAB PHONE NUMBER

YOUR LABORATORY ADDRESS 2
LAB FAX NUMBER

Sample ID: 1 Patient Name:
Run Date/Time: 04/18/2001 04:30:55 PM Patient ID: Collect Date/Time:
Seq#: 391 Gender: Unknown DOB: Physician:
OPR: Admin Age: Location:
Flagging Set: Standard Range
Comments:

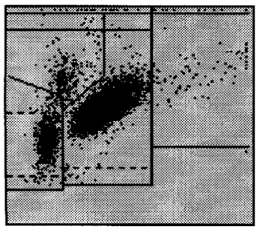
Startup status **Startup Not Done**

				Range
WBC	6.9		10e3/µL	4.0 / 11.0
RBC	4.74		10e6/µL	3.80 / 6.50
HGB	14.6		g/dL	12.0 / 18.0
HCT	43.2		%	36.0 / 54.0
MCV	91		fL	76 / 96
MCH	30.8		pg	27.0 / 32.0
MCHC	33.8		g/dL	31.0 / 35.0
RDW	10.9	L	%	11.0 / 16.0
PLT	259		10e3/µL	150 / 400
MPV	7.6		fL	6.0 / 10.0
@PCT	0.196		%	0.150 / 0.300
@PDW	11.8	L	%	15.0 / 17.0

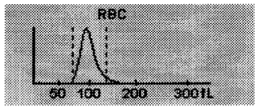
				Range
NE	72.0	H	%	45.0 / 70.0
LY	20.8		%	20.0 / 50.0
MO	4.9		%	3.0 / 10.0
EO	1.9		%	1.0 / 5.0
BA	0.4		%	0.0 / 0.5
@ATL	0.7		%	0.0 / 2.0
@IMM	0.9		%	0.0 / 2.0
NE#	4.98		10e3/µL	2.00 / 7.50
LY#	1.44	L	10e3/µL	1.50 / 4.00
MO#	0.34		10e3/µL	0.20 / 0.80
EO#	0.13		10e3/µL	0.04 / 0.40
BA#	0.03		10e3/µL	0.02 / 0.10
@ATL#	0.05		10e3/µL	0.00 / 0.20
@IMM#	0.06		10e3/µL	0.00 / 0.20

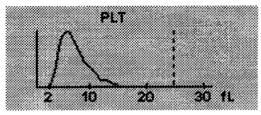
Flags and Messages

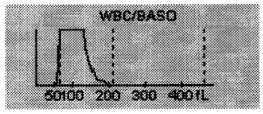
Vol



Abs







Microscopic Examination

Neutrophils	_____	Metamyelocytes	_____	Anisocytosis	_____	Retics	_____
Bands	_____	Myelocytes	_____	Hypochromia	_____	Sed. Rate	_____
Lymphocytes	_____	Promyelocytes	_____	Polychromasia	_____		
Monocytes	_____	Blast	_____	Poikilocytosis	_____		
Eosinophils	_____	Atyp. Lymph	_____	Microcytosis	_____		
Basophils	_____	NRBC's	_____	Macrocytosis	_____		

Comment : _____ Requested by : _____

_____ Reviewed by : _____

@For Research Use Only. Not for use in diagnostic procedures (RUO).
Out of Action Range XXX Out of Patient Range XXX

Printed 14/03/2001 11:08:10 AM

Measurements and Computation

- Impedance is used to determine WBC, Plt, RBC, and BA.
- Photometry using cyanmethemoglobin method with 550nm diode light source is used to determine Hgb.
- Impedance and light absorbance are used to determine NE, LY, MO, EO, ATL, and IMM.
- Data that was directly measured is used to compute Hct, MCV, MCH, MCHC, RDW, MPV, Pct, and PDW.

Counting Aperture Diameters

WBC/BASO: 80 µm
DIFF: 60 µm
RBC/Plt: 50 µm

Reagent Consumption

Table 3.1 shows the instrument's reagent consumption by cycle.

Table 3.1 Reagent Consumption by Cycle in mL

Cycle	Reagent					Approximate Duration
	Diluent	WBC Lyse	Rinse	Fix	Hgb Lyse	
CBC	22.6	2.1	0.9	–	0.4	60 sec
CBC/DIFF	28.5	2.1	0.9	1.0	0.4	60 sec
Startup†	65.4	2.1	3.7	1.0	1.4	4 min 50 sec
Shutdown	27.0	–	14	–	1.0	3 min
Prime Diluent	44.9	–	–	–	–	3 min 10 sec
Prime Rinse	–	–	24.8	–	–	1 min 20 sec
Prime Fix	–	–	–	23.6	–	1 min 10 sec
Prime WBC Lyse	–	23.6	1.1	–	–	2 min 20 sec
Prime Hgb Lyse	2.1	–	–	–	8.4	1 min 30 sec
Prime All Reagents	49.0	24.0	25.1	24	8.2	6 min
Autoclean	13.4	1.0	1.0	1.0	0.3	1 min 35 sec
System Reset Cycle	25.4	–	1.4	–	1.0	1 min 50 sec
Clean Dil Cycle*	6.5	–	–	–	–	10 sec

†For one background count only. The maximum is three.
** Cycle runs automatically after 4 hr 30 min of non-use.*
– indicates not applicable.

Environmental Protection

Removal and recycling of this instrument must be done by a properly qualified laboratory in accordance with local legislation.

3.2 PERFORMANCE SPECIFICATIONS

Performance specifications indicate targeted performance based on established ranges and parameters.

The stated performance specifications apply to an instrument that has been properly maintained as indicated in ***Chapter 11, DIAGNOSTICS***, and one that uses only the recommended reagents listed in ***Recommended Reagents***.

Reproducibility

Reproducibility (Table 3.2) is based on 20 consecutive replicate runs from one normal, fresh whole-blood sample without flags.

Table 3.2 Reproducibility Specifications

Parameter	CV%	Test Level
WBC	<2.0%	10.0x10^3/µL
RBC	<2.0%	5.00x10^6/µL
Hgb	<1.0%	15.0 g/dL
Hct	<2.0%	45.0%
Plt	<5.0%	300.0x10^3/µL
MCV	<1.0%	90 fL

Linearity

Linearity is assessed using a commercially-available low-range and full-range linearity test kit. When analyzed and results computed according to the manufacturer's instructions, the results will be within the limits in Table 3.3.

Table 3.3 Linearity Specifications

Parameter	Units	Linearity Range	Difference (Whichever is Greater)
WBC	10^3/µL	0.4 to 91.3	±0.2 or ±3.0%
RBC	10^6/µL	0.30 to 8.00	±0.07 or ±5.0%
Plt	10^3/µL	10.0 to 1,000	±10.0 or ±10.0%
Hgb	g/dL	0.0 to 22.0	±0.3 or ±2.0%
Hct	%	1.8 to 55.9 56.0 to 63.8	±2.0 or ±3.0% ±5.0 or ±5.0%

Accuracy

Accuracy (Table 3.4) is assessed by duplicate analysis of normal and clinical specimens less than eight hours old when compared to an automated hematology analyzer that has been properly calibrated and maintained according to the manufacturer's recommendation.

Table 3.4 Accuracy Specifications

Parameter	Correlation r
WBC	>0.95
RBC	>0.95
Hgb	>0.95
Hct	>0.95
Plt	>0.95

Carryover

Carryover (Table 3.5) is assessed by analyzing whole blood with high values followed by a whole blood sample with low values. Each sample is run consecutively in triplicate.

Carryover is calculated as follows:

$$\text{Carryover} = \frac{\text{Low 1 - Low 3}}{\text{High 1 - Low 3}} \times 100$$

Table 3.5 Carryover Specifications

Parameter	Carryover
WBC	<2.0%
RBC	<2.0%
Plt	<2.0%
Hgb	<2.0%

Reportable Range

The reportable range (Table 3.6) is the range of results that the instrument displays, prints, and transmits. Results between the linear range and the reportable range will be flagged.

Table 3.6 Reportable Range

Parameter	Units	Reportable Range
WBC	$10^3/\mu L$	0.0 – 100.0
RBC	$10^6/\mu L$	0.00 – 10.00
Plt	$10^3/\mu L$	0.0 – 1500.0
Hct	%	0.0 – 80.0
Hgb	g/dL	0.0 - 30.0

3.3 PERFORMANCE CHARACTERISTICS

Performance characteristics indicate actual performance.

Reproducibility

Reproducibility was measured to show precision for a normal WBC count. Table 3.7 shows the precision values based on 20 replicate samples that were analyzed consecutively on the same instrument from one normal, fresh, whole-blood sample with a normal WBC and without flags.

Table 3.7 Reproducibility Characteristics From a Normal Sample with a Normal WBC Count

Parameter	Mean	Standard Deviation (SD)	CV%
WBC	10.5	0.14	1.32
RBC	4.74	0.04	0.88
Hgb	14.5	0.08	0.56
Hct	42.8	0.43	0.99
MCV	90	0.30	0.32
Plt	310	7.8	2.52
NE%	50.2	0.46	0.90
LY%	41.0	0.43	1.04
MO%	3.9	0.18	4.60
EO%	3.5	0.18	5.14
BA%	1.3	0.09	6.96

Accuracy

Accuracy (Table 3.8) for the CBC and DIFF parameters was defined as agreement between the comparator instrument and the A^{C}•T 5diff CP analyzer using normal and clinical specimens less than eight hours old covering the expected range of performance.

Table 3.8 Accuracy Characteristics

Parameter	Correlation r
WBC	0.99
RBC	0.99
Hgb	0.99
Hct	0.99
Plt	0.99
NE%	0.99
LY%	0.99
MO%	0.96
EO%	0.98

Carryover

Carryover (Table 3.9) was assessed by analyzing whole blood with high values followed by a whole-blood sample with low values. Each sample was run consecutively in triplicate.

Carryover is calculated as follows:

$$\text{Carryover} = \frac{\text{Low 1 - Low 3}}{\text{High 1 - Low 3}} \times 100$$

Table 3.9 Carryover Characteristics

Parameter	Units	High Level	Low Level	Carryover
WBC	$10^3/\mu L$	73.4	0.90	-0.09
RBC	$10^6/\mu L$	7.20	1.69	0.66
Plt	$10^3/\mu L$	822	35.0	0.04
Hgb	g/dL	20.7	4.83	0.21

Sample Stability

The following tables show the average results for specimens from five normal donors collected in K3EDTA. The specimens were stored at room temperature and cold temperature. For this study, room temperature was 72 - 73ºF (22 - 23ºC) and cold temperature was 37 - 39ºF (3 - 4ºC). Each sample was analyzed in duplicate at the time interval indicated (hours) and the second run used to establish the mean. The cold stored samples were removed from the refrigerator, mixed, and analyzed within five minutes.

Table 3.10 Sample Stability, Room Temperature

Parameter	T1	T4	T8	T24	T48
WBC Mean (x10³/µL)	6.52	6.48	6.48	6.50	6.32
RBC Mean (x106/µL)	4.620	4.606	4.602	4.616	4.634
HGB Mean (Hgb)	13.70	13.62	13.60	13.62	13.66
HCT Mean (%)	41.04	40.72	40.68	41.10	40.80
MCV Mean (fL)	88.60	88.20	88.40	89.00	88.00
RDW Mean (%)	13.08	13.18	13.18	13.44	13.12
PLT Mean (x10³/µL)	355.4	354.6	354.2	353.4	348.0
MPV Mean (fL)	8.18	8.62	8.60	9.02	9.52
NE% Mean	54.10	53.40	53.84	53.12	56.24
LY% Mean	31.96	32.84	32.32	33.22	33.86
MO% Mean	7.60	7.60	7.44	7.44	4.42
EO% Mean	5.64	5.48	5.68	5.60	4.94
BA% Mean	0.70	0.68	0.72	0.62	0.54
NE# Mean (x10³/µL)	3.60	3.52	3.56	3.52	3.63
LY# Mean (x10³/µL)	2.02	2.06	2.02	2.09	5.70
MO# Mean (x10³/µL)	0.49	0.48	0.48	0.47	0.27
EO# Mean (x10³/µL)	0.38	0.37	0.39	0.38	0.32
BA# Mean (x10³/µL)	0.04	0.04	0.04	0.04	0.03

Table 3.11 Sample Stability, Cold Temperature

Parameter	T1 at Room Temperature	T4	T8	T24	T48
WBC Mean (x10³/µL)	6.52	6.60	6.54	6.38	5.92
RBC Mean (x106/µL)	4.620	4.610	4.604	4.606	4.618
HGB Mean (Hgb)	13.70	13.64	13.64	13.64	13.64
HCT Mean (%)	41.04	40.82	40.70	40.70	40.66
MCV Mean (fL)	88.60	88.40	88.40	88.20	87.80
RDW Mean (%)	13.08	13.28	13.28	13.72	13.66
PLT Mean (x10³/µL)	355.4	352.0	352.2	342.6	350.4
MPV Mean (fL)	8.18	8.34	8.42	8.78	8.82
NE% Mean	54.10	54.46	54.00	53.98	51.48
LY% Mean	31.96	31.66	32.02	31.76	32.94
MO% Mean	7.60	7.32	7.02	7.40	8.30
EO% Mean	5.64	5.78	6.14	6.06	6.30
BA% Mean	0.70	0.78	0.82	0.80	0.98
NE# Mean (x10³/µL)	3.60	3.67	3.61	3.51	3.15
LY# Mean (x10³/µL)	2.02	2.02	2.03	1.95	1.85
MO# Mean (x10³/µL)	0.49	0.48	0.45	0.46	0.49
EO# Mean (x10³/µL)	0.38	0.39	0.41	0.41	0.38
BA# Mean (x10³/µL)	0.04	0.05	0.05	0.05	0.05

3.4 LIMITATIONS

Maintenance

Failure to properly execute the maintenance procedures in ***Chapter 11, DIAGNOSTICS*** may compromise the instrument's reliability.

Blood Specimens

If any abnormal test result (including flagged results or results outside the normal range) occur, use reference methods or other standard laboratory procedures to verify the results. For additional information, see ***Heading 3.5, INTERFERING SUBSTANCES***.

3.5 INTERFERING SUBSTANCES

Table 3.12 shows a list of known limitations of automated blood cell counters that use impedance and light absorbance as measurement principles.

Table 3.12 Interfering Substances

Parameter	Interfering Substance
WBC	Unlysed RBCs: In rare instances, the erythrocytes in the blood sample may not completely lyse and are detected on the WBC histogram with an *WBC flag or as an elevated baseline on the lymphocytes. Non-lysed RBCs will cause a falsely elevated WBC count. Multiple myeloma: The precipitation of proteins in multiple myeloma patients may cause elevated WBC counts. Leukemia: A very low WBC count may result in this disease state due to the possible fragility of the leukocytes; some of these cells may be destroyed during counting. WBC fragments will also interfere with the WBC DIFF parameters. Chemotherapy: Cytotoxic and immunosuppressive drugs may increase the fragility of the leukocytes, which may cause low WBC counts. Cryoglobulins: Increased levels of cryoglobulin that may be associated with myeloma, carcinoma, leukemia, macroglobulinemia, lymphoproliferative disorders, metastic tumors, autoimmune disorders, infections, aneurysm, pregnancy, thromboembolic phenomena, diabetes, and so forth, which can elevate the WBC, RBC, or Plt counts and the Hgb concentration. The specimen must be warmed to 37°C (99°F) in a water bath for 30 minutes and reanalyzed immediately (analyzer or manual method). Agglutinated WBCs: Leukoagglutination.
RBC†	Agglutinated RBCs: May cause a falsely low RBC count. Blood samples containing the agglutinated RBCs may be suspected by elevated MCH and MCHC values and shown by examination of the stained blood film. Cold agglutinins: IgM immunoglobulins elevated in cold agglutinin disease may lower RBC and Plt counts and increase MCV.

Table 3.12 Interfering Substances *(Continued)*

Parameter	Interfering Substance
Hgb	Turbidity of the blood sample: Any number of physiologic and/or therapeutic factors may produce falsely elevated Hgb results. To obtain accurate Hgb results when increased turbidity of the blood sample occurs, determine the cause of the turbidity and follow the appropriate method below: • Elevated WBC: An extremely elevated WBC will cause excessive light scatter. If this occurs: 1. Use the reference (manual) methods. 2. Centrifuge the diluted sample. 3. Measure the supernatant fluid with a spectrophotometer. • Elevated lipids*:* Elevated lipids in the blood sample will give the plasma a milky appearance. This condition can occur with hyperlipidemia, hyperproteinemia (as in gammapathies), and hyperbilirubinemia. Accurate hemoglobin determinations can be achieved by using reference (manual) methods and a plasma bank. • Increased turbidity: This may be seen in cases where the RBCs are resistant to lysing. This condition will cause a falsely elevated Hgb result but may be detected by observing the abnormal MCH, MCHC values, and the increased baseline on the leading edge of the WBC histogram. Erroneous Hgb results will cause the results of MCH and MCHC to also be erroneous. • Fetal bloods*:* The mixing of fetal and maternal blood may produce a falsely elevated Hgb value.
Hct	RBC agglutination**:** May produce erroneous Hct and MCV values. RBC agglutination may be detected by observing abnormal MCH and MCHC values, and by examining the stained blood film. Use the manual method to obtain an accurate Hct value.
MCV	RBC agglutination: May produce an erroneous MCV value. RBC agglutination may be detected by observing abnormal MCH and MCHC values, and by examining the stained blood film. Use the manual method to obtain an accurate MCV value. Excessive numbers of large platelets: This condition and/or the presence of an excessively high WBC count may interfere with the accurate determination of the MCV value. Carefully examine the stained blood film to detect the problem.
MCH	MCH is determined according to the Hgb value and the RBC count, which means that anything listed as an interfering substance for Hgb and/or RBC will impact MCH and may cause erroneous MCH values.
MCHC	MCHC is determined according to the Hgb and Hct values, which means that anything listed as an interfering substance for Hgb and/or Hct will impact MCHC and may cause erroneous MCHC values.
RDW	RDW is determined according to the RBC count and may be impacted by the following conditions: • Agglutinated RBCs: May cause a falsely low RBC count and erroneous RDWs. Blood samples containing the agglutinated RBC may be detected by observing abnormal MCH and MCHC values and by examining the stained blood film. • Nutritional deficiency or blood transfusion: May cause elevated RDW results due to iron, cobalamin, and/or folate deficiencies.

Table 3.12 Interfering Substances *(Continued)*

Parameter	Interfering Substance
Plt	Very small RBCs (microcytes), RBC fragments (schizocytes), and WBC fragments: May interfere with the proper counting of platelets and cause elevated Plt counts. Agglutinated RBCs: May trap platelets, causing an erroneously low Plt count. The presence of agglutinated RBCs may be detected by observing abnormal MCH and MCHC values and by examining the stained blood film. Excessive numbers of large platelets**:** May cause an erroneously low Plt count since these large platelets may exceed the upper threshold for the Plt parameter are not counted. Chemotherapy: Cytotoxic and immunosuppressive drugs may increase the fragility of cells, which may affect the proper counting of platelets. Use the manual (reference) method to obtain an accurate Plt count. Hemolysis: Hemolysed specimens contain RBC stroma which may elevate Plt count. Lipemic samples and/or elevated triglycerides and/or elevated cholesterol: May interfere with the proper counting of platelets. ACD (acid-citrate-dextrose) blood**:** Blood anticoagulated with ACD may contain clumped Plt which could depress the Plt count. Note that, in some patients, platelets can aggregate in the presence of EDTA because of the occurrence of platelet-specific antibodies. This may cause an erroneously low or decreased platelet count. Plt Agglutination: Clumped platelets may cause a decreased Plt count and/or elevated WBC count; *WBC, SL, and SL1 flags may be generated. Reanalyze the specimen as follows: 1. Recollect the specimen in sodium citrate anticoagulant to prevent platelet agglutination. 2. Reanalyze the specimen for only the Plt count. 3. Correct the final Plt result for the effect of the sodium citrate dilution.
MPV‡	Giant platelets: May exceed the upper threshold of the Plt parameter and may not be counted as platelets. Consequently, these larger platelets will not be included in the instrument's calculation of MPV. Very small RBCs (microcytes), RBC fragments (schizocytes), and WBC fragments: May interfere with the proper counting of platelets. Agglutinated RBCs: May trap platelets, causing an erroneous MPV result. You may be able to detect the presence of agglutinated RBCs by observing abnormal MCH and MCHC values and by examining the stained blood film. Chemotherapy: May also affect the sizing of platelets.
NE#, NE%	The neutrophil count is derived from the WBC count. The presence of excessive eosinophils, metamyelocytes, myelocytes, promyelocytes, blasts, and plasma cells may interfere with an accurate neutrophil count.
LY#, LY%	The lymphocyte count is derived from the WBC count. The presence of erythroblasts, certain parasites, and RBCs that are resistant to lysis may interfere with an accurate LY count. Interfering substances pertaining to WBC also pertain to the LY# and LY%.
MO#, MO%	The mononuclear cell count absolute is derived from the WBC count. The presence of large lymphocytes, atypical lymphocytes, blasts, and an excessive number of basophils may interfere with an accurate monocyte count. Interfering substances pertaining to WBC also pertain to the MO# and MO%.

Table 3.12 Interfering Substances *(Continued)*

Parameter	Interfering Substance
EO#, EO%	The eosinophil cell count is derived from the WBC count. The presence of abnormal granules (degranulated areas, toxic granules, and so forth) may interfere with the eosinophil count. Interfering substances pertaining to WBC also pertain to the EO# and EO%.
BA#, BA%	The basophil cell count is derived from the WBC count. Interfering substances pertaining to WBC also pertain to the BA# and BA%.

†The RBC dilution contains all formed elements in the blood, erythrocytes, leukocytes, and platelets. During the counting of the RBCs, platelets are not counted if their size falls below the RBC minimum threshold.

‡Blood samples collected in EDTA will not maintain a stable MPV because platelets swell depending on the time post-collection and storage temperature.

4.1 DEFINITIONS

Warnings

Anything that can cause user injury is considered a hazard and is noted in the text as WARNING. Warnings appear where needed throughout this manual.

Cautions

Anything that can cause instrument damage is considered a caution and is noted in the text as CAUTION. Cautions appear where needed throughout this manual.

Importants

Anything that can cause misleading results or data corruption is considered important and is noted in the text as IMPORTANT. Importants appear where needed throughout this manual.

Attention

An ATTENTION provides additional information to be considered when performing a procedure.

4.2 SAFETY PRECAUTIONS

Electronic

WARNING Risk of personal injury from electronic shock. Electronic components can shock and injure you. To prevent possible injury or shock, do not tamper with the instrument and do not remove any components (covers, doors, panels, and so on) unless otherwise instructed within this document.

Biological

WARNING Risk of personal injury or contamination. If you do not properly shield yourself while using or servicing the instrument, you may become injured or contaminated. To prevent possible injury or biological contamination, you must wear proper laboratory attire, including gloves, a laboratory coat, and eye protection.

Use universal precautions when working with pathogenic materials. Means must be available to decontaminate the instrument and to dispose of biohazardous waste.

Moving Parts

WARNING Risk of personal injury. Operating the instrument with doors and/or covers open can cause personal injury. When you operate the instrument, be sure all covers and doors are closed.

4.3 OPERATIONAL HAZARDS

Safety symbols alert you to potentially dangerous conditions. These symbols, together with text, apply to specific procedures and appear as needed throughout this manual.

Symbol	Warning Condition	Action
	Biohazard.Consider all materials (specimens, reagents, controls, calibrators, and so forth) and areas these materials come into contact with as being potentially infectious.	Wear standard laboratory attire and follow safe laboratory procedures when handling any material in the laboratory.
	Probe hazard. The probe is sharp and may contain biohazardous materials, such as controls and calibrators.	Avoid any unnecessary contact with the probe and probe area.
	Electrical shock hazard. Possibility of electrical shock when instrument is plugged into the power source.	Before continuing, unplug the A^{C}•T 5diff CP analyzer from the electrical outlet.

5.1 GENERAL

After your system is set up and configured at installation, use this section as an overview.

5.2 POWER UP/POWER DOWN

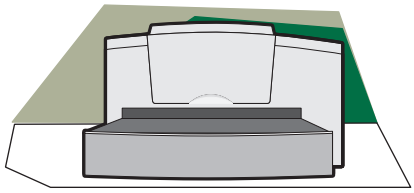
To ensure the correct operation of the system, it is important that the power up and power down sequences be done in the proper order.

Power Up the System

1 Check the waste container to determine if it needs to be replaced. If so, do ***Replacing the Waste Container***.

2 Verify that the printer is ready and has paper. Refer to the printer manual for details, if necessary.

Note: Your printer may be different from what is shown here.



3 Verify that the Analyzer's ac power cord is plugged into a power source.

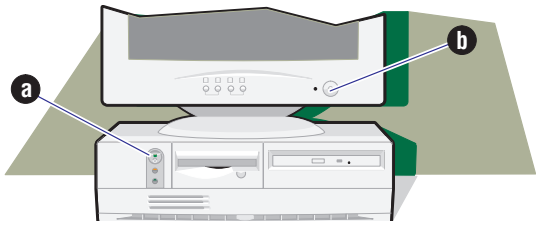
If the ac power cord is unplugged, plug the cord into the instrument (at the back panel, in the lower right corner) and/or into an appropriate ac wall outlet.

4 Turn the Workstation computer on.

a. Turn the PC on.

b. Turn the monitor on.

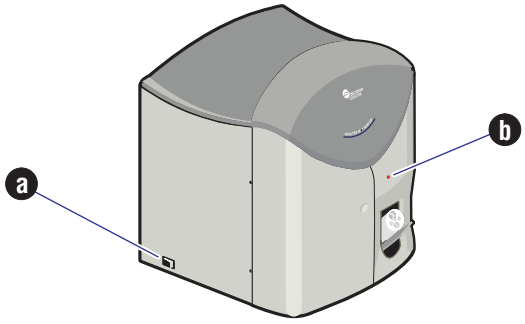
Allow sufficient time for the computer to complete its internal checks.



5 At the Analyzer:

a. Turn the power ON/OFF switch ON.

b. Verify that the red LED remains illuminated.



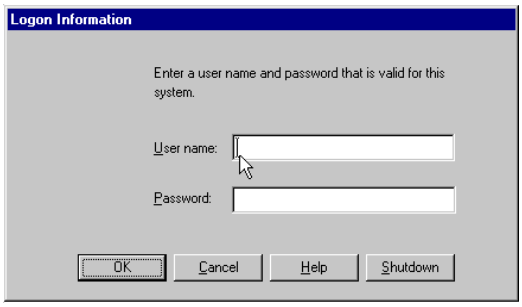
6 Log on to the Workstation:

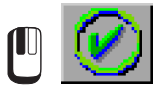
a. When the Begin Logon box appears, simultaneously press Ctrl + Alt + Delete.

b. Type User name `BCI` and press Tab.

c. Type Password `123`.

d. Press Enter or **OK**.



7 Type your Operator ID and press Enter or  .

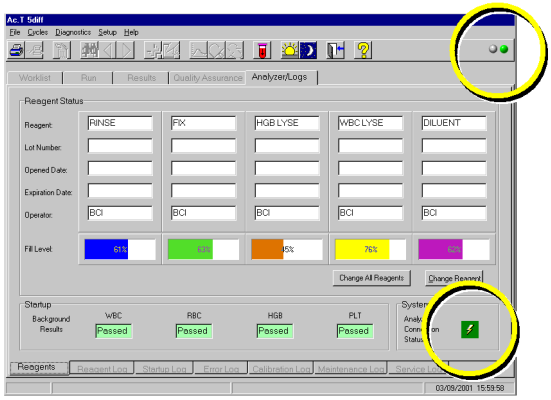
Note: Your Operator ID is a 3 character alphanumeric code that identifies you as the operator. Use your initials or any other 3-character combination that will distinguish you from other users.

8 At the Workstation:

a. Wait for the Analyzer/Logs window to appear.

b. Wait about 30 seconds for the Analyzer and Workstation to communicate and to connect.

9 Verify that the Analyzer and Workstation connection is made:

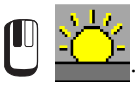


a. Verify that appears in the lower right corner of the screen.

Note: indicates that the Analyzer and Workstation connection is not made. If the Analyzer and Workstation fail to connect, repeat steps 1 through 7. Contact a Beckman Coulter representative if the problem persists.

b. Verify that the green LED is illuminated (“ready”).

10 Startup automatically runs if the automatic Startup feature is enabled and the instrument is powered on,

If automatic Startup at power up is disabled,  .

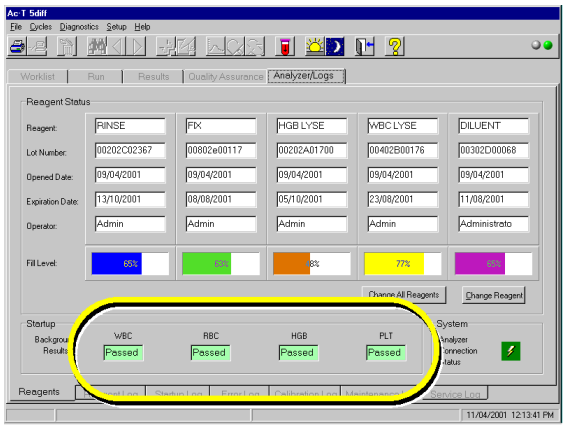
11 Allow Startup to finish.

12 Review the Startup results status:

a. **Analyzer/Logs** if the screen is not already displayed.

b. Review the Startup results:

- If *Passed* appears, go to step 14.
- If *Failed* appears, go to step 13.



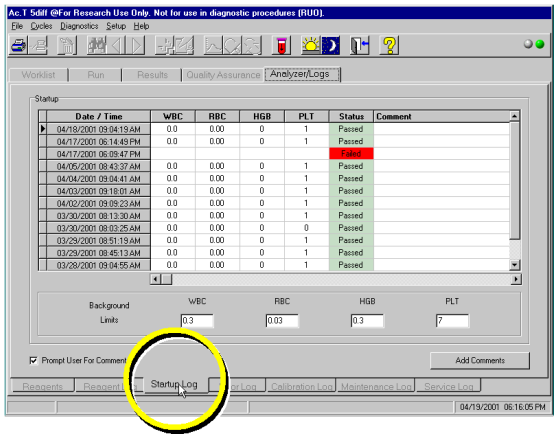
13 If *Failed* appears on Startup result.

a. **Startup Log** tab and evaluate the numeric results.

b. or **Cycles** ▸▸ **Startup** to initiate another Startup routine.

c. If the Startup continues to fail, contact a Beckman Coulter representative.

Note: the **Run** tab to view the Startup results.


Ac.T 5diff @For Research Use Only. Not for use in diagnostic procedures (RUO).
File Cycles Diagnostics Setup Help
Worklist Run Results Quality Assurance Analyzer/Logs
Startup
Date / Time WBC RBC HGB PLT Status Comment
04/18/2001 09:04:19 AM 0.0 0.00 0 1 Passed
04/17/2001 06:14:49 PM 0.0 0.00 0 1 Passed
04/17/2001 06:09:47 PM Failed
04/05/2001 08:43:37 AM 0.0 0.00 0 1 Passed
04/04/2001 09:04:41 AM 0.0 0.00 0 1 Passed
04/03/2001 09:18:01 AM 0.0 0.00 0 1 Passed
04/02/2001 09:09:23 AM 0.0 0.00 0 1 Passed
03/30/2001 08:13:30 AM 0.0 0.00 0 1 Passed
03/30/2001 08:03:25 AM 0.0 0.00 0 0 Passed
03/29/2001 08:51:19 AM 0.0 0.00 0 1 Passed
03/29/2001 08:45:13 AM 0.0 0.00 0 1 Passed
03/29/2001 09:04:55 AM 0.0 0.00 0 1 Passed
Background
Limits
WBC 0.3
RBC 0.03
HGB 0.3
PLT 7
Prompt User For Comment
Add Comments
Reagents Reagent Log Startup Log Error Log Calibration Log Maintenance Log Service Log
04/19/2001 06:16:05 PM

14 The Startup log automatically prints (in tabular format) if Auto-Print is enabled.

If Auto-Print is disabled, .

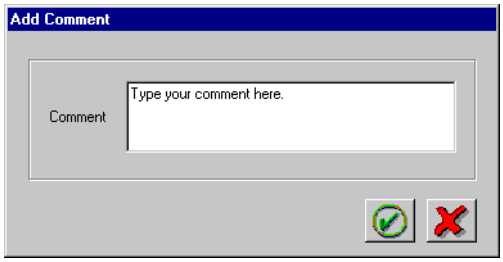
15 Add comments to the Startup log, if desired:

a. If the **Add Comments** box appeared automatically, type your comments.

To access the **Add Comments** box,

Startup Log tab ▸▸ **Add Comments** button then type your comments.

b. to save your comments.



IMPORTANT Risk of inaccurate results if the Analyzer is not properly prepared. Follow the prompts, if any, on the screen to perform either a Startup or Mini Prime to prepare the Analyzer. It is not necessary to do both.

16 If the system has remained idle for a certain period of time, you will be prompted to do a Startup or a Mini Prime.

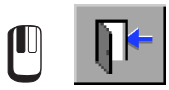
Power Down the System

Before performing certain replacement procedures, you will be instructed to power down the system to prevent personal injury from electric shock.

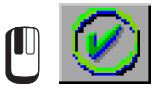
There is a proper power down sequence that you must follow to prevent damaging the system.

---

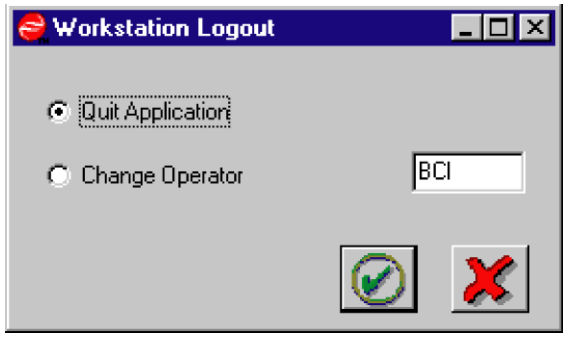
1 Log out of the Workstation:

a.  .

b. Select Quit Application.

c. Press Enter or  .

d. Wait while the Workstation closes its program.



---

2 When the Begin Logon box appears, simultaneously press Ctrl + Alt + Delete.

---

3 **Shut Down**.

---

4 Verify that only **Shut Down** is selected.

---

5 **OK**.

"*It is now safe to turn off your computer*" appears.

6 Turn off the Workstation.

Note: Do not **Restart**.

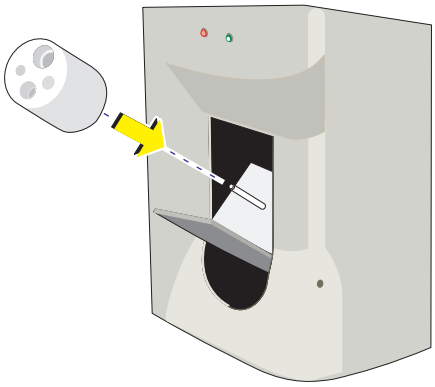
7 Turn off the Analyzer.

ATTENTION: If you are doing a replacement or maintenance procedure that requires you to open the Analyzer panels, unplug the ac power cord. Either remove the cord from the instrument (at the back panel, in the lower right corner) or unplug it from the ac outlet.

5.3 PLACING THE TUBE HOLDER IN THE ANALYZER

Do this procedure to place a tube holder in the Analyzer.

1 Slide the tube holder over the metal shaft in the Analyzer.



2 Rotate the tube holder until it is properly seated.

5.4 POSITIONING TUBES IN TUBE HOLDERS

Some procedures in this manual require you to place a tube (or vial) into the tube holder and start analysis. There are three factors to be aware of:

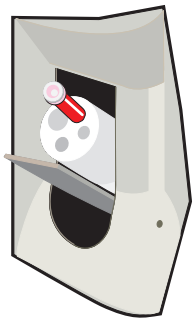
1. The manufacturer and tube name of the cap pierceable tube (vial) that you are using. See ***Appendix D, TUBE LIST***.
2. The position of the tube in the tube holder. See ***Tube Holders*** in Chapter 1.
3. The position of the tube holder in the Analyzer. See ***Position of Tube Holder in the Analyzer*** in this section.

Position of Tube Holder in the Analyzer

There is one pierce position in the Analyzer, which means that tube holder must be rotated such that the tube to be pierced is in the pierce position (12:00 o'clock),

---

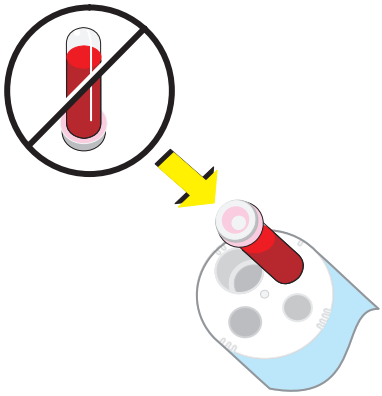
1 The tube holder door automatically opens when the system is ready.



WARNING Risk of exposure to biohazardous material:

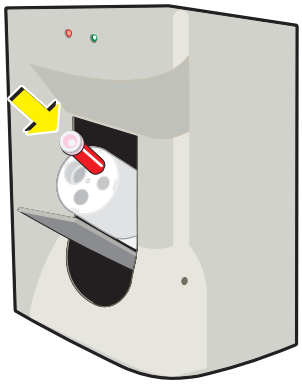
1) If you insert an uncapped tube or vial into the tube holder; the contents may spill out of the tube or vial, thereby creating a biohazardous condition. If the tube or vial can be cap pierced, then ensure that the cap is secure before inserting the tube or vial into the tube holder.

2) If you insert a tube or vial upside down into the tube holder. Always insert the tube bottom first into the holder.

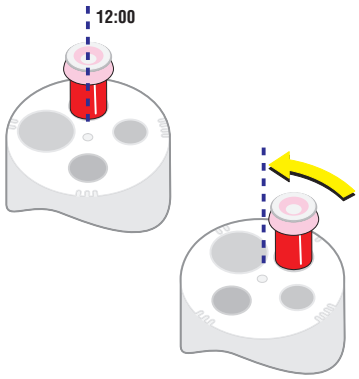


2 Insert the tube (vial) into the appropriate position in the tube holder.

For information on the correct position of each tube within the tube holder as defined in ***Table D.1, Specimen Tubes for Use with the Tube Holders***.



IMPORTANT Risk of erroneous results if the sample tube is not placed in the holder correctly and if the tube holder is not positioned correctly in the instrument. Ensure that the tube is placed in the 12:00 o'clock pierce position within the tube holder.



3 Ensure that the tube is in the pierce position (12:00 o'clock) within the tube holder.

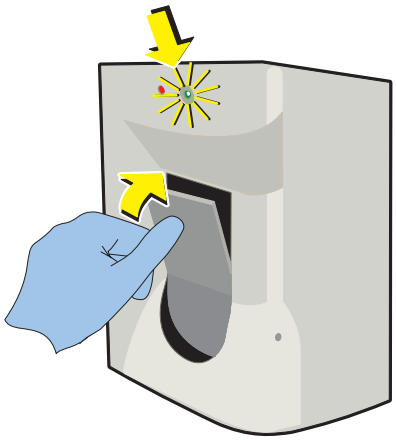
- If the tube is in the pierce position within the holder, do step 4.
- If the tube is not in the pierce position within the holder, rotate the holder until the tube is in the pierce position.

If the tube holder is not in the correct position when you close the door, an error message will appear.

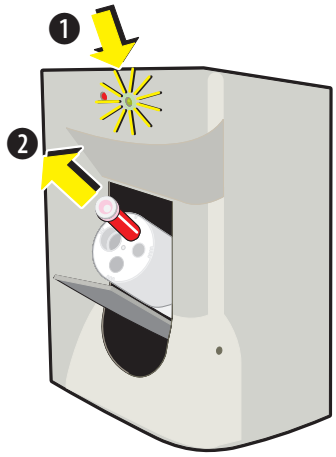
4 Close the tube holder door.

The red and green LEDs flash during analysis.

- When the red LED remains illuminated, the system is busy analyzing the sample.
- When the green LED remains illuminated, the instrument is ready for the next analysis.



5 When the LED is green (❶) and the tube holder door opens (❷), remove the tube/vial.



5.5 USING THE ONLINE HELP SYSTEM

Your COULTER® A^{C}•T™ 5diff CP system provides an online Help system that:

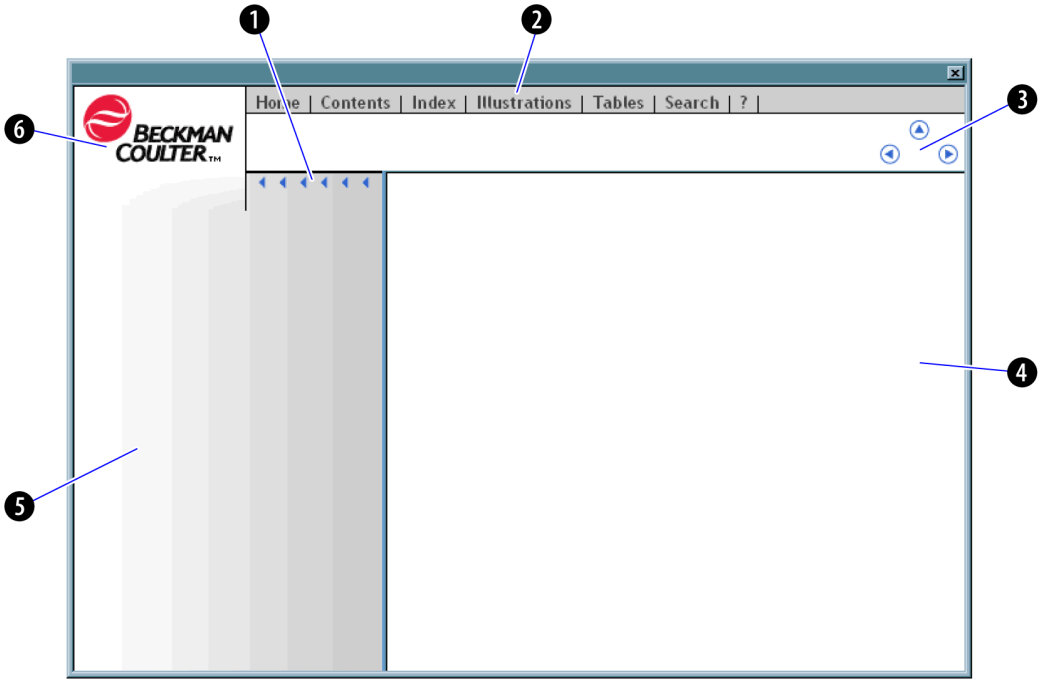
- allows you to search for information on specific system-related topics through the **Contents** option, and
- allows you to print this Operator's Manual (Instructions For Use) in whole or in part through the **Print Manual** option.

The Help system is an electronic version of the Operator's Manual and includes a table of contents, an index for finding information quickly, and a glossary of definitions.

When you access the Help menu, there are three options available: **Contents**, **Print Manual**. and **About**.

Figure 5.1 defines the screen that appears when you select **Contents** from **Help** menu.

Figure 5.1 Help Screen



1. Closes the topics pane when selected.
2. Displays the menu options for the onlilne Help.
3. Allows you to navigate through the Help.
4. Displays the contents of the selected Help topic.
5. Displays the topics (contents, illustrations, or tables).
6. Displays the Index letters (when Index is selected).

Accessing Online Help

Do this procedure to access the online Help system.

-

  OR

- **Help** ▸▸ **Contents**.

Note: If you cannot access the online Help system, contact your Beckman Coulter Representative.

Moving/Resizing the Help Screen

If the Help screen needs to be moved or resized, do this procedure.

---

1 Access online Help.

---

2 To move the Help window:

a. the title bar and hold down the left mouse button.

b. Move the mouse to drag the window to a new location.

- Release the mouse button.

---

3 To resize the Help window:

a. Move the cursor over the border until the arrows appears.

b. and drag to resize it.

c. Release the mouse button.

Opening/Closing the Topics Pane

To maximize the contents pane (where text and graphics appear), you may want to close the topics pane (where topics appear). Do the following procedure to open/close the topics pane.

---

1 Access online Help.

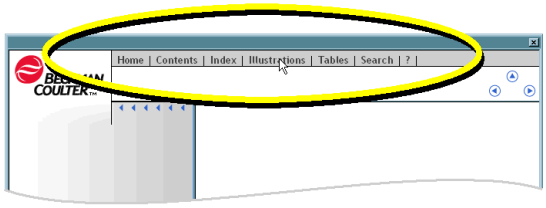
---

2 the arrows to close the topics pane.

---

3 any of the following option to re-open the topics pane:

- **Contents**,
- **Index**,
- **Tables**,
- **Illustrations**, or
- **Search**.



Viewing Help Topics

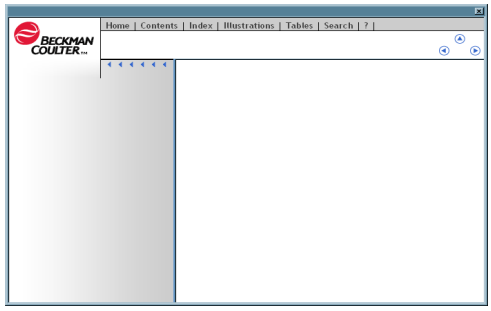
Do this procedure to view topics within the Help system.

---

1 Access online Help.

---

2 Navigate through Help as needed:



- **Contents** to browse through topics by heading.
- **Index** to see a list of index entries.
- **Tables** to see a list of tables.
- **Illustrations** to see a list of illustrations.
- **Search** to search for words or phrases.
- **Home** to return to main Help screen.

---

3 Move through topics as needed:

- to display the previous topic in the sequence.
- to display the next topic in the sequence.
- to display the previous hyperlink.

4 View referenced or related topics:

- the highlighted words in a topic body to link directly to the referenced topic.
- a word in the highlighted hierarchy – at the top of the topic – to change topic levels. The current topic's position also appears in the hierarchy.

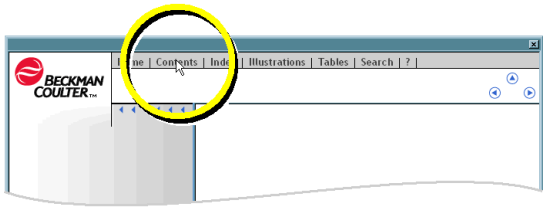
5 To view information not visible in the Help window, scroll through the window by using the scroll bar.

Using the Contents Option

The contents option displays is a list of subject headings within the manual.

1 Access online Help.

2 **Contents** to browse through topics by heading.



3 + to expand the headings.

4 the topic you want to view.

Using the Index Option

The index displays a list of entries sorted alphabetically. It is probably the best way to find information about a specific concept or system feature.

1 Access online Help.

2 **Index**.

3 the letter for which you want to see index entries.

A list of entries that start with the letter you selected appears.

4 Scroll through the topics as needed.

5 a number after the index entry to display information about that topic.

Using the Tables Option

The tables option displays a list of tables within the manual.

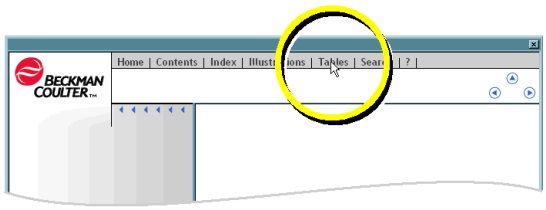
---

1 Access online Help.

---

2 **Tables**.

A list of tables appears.



---

3 Scroll through the tables to locate the table you want to view.

---

4 the table to display it on the screen.

Using the Illustrations Option

The illustrations option displays a list of illustrations within the manual.

---

1 Access online Help.

---

2 **Illustrations**.

A list of illustrations appears.

3 Scroll through the illustrations to locate the illustration you want to view.

4 the illustration to display it on the screen.

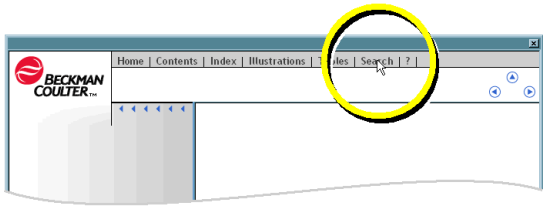
Using the Search Option

The search option allows you to locate help topics by searching for words or phrases the topics contain.

1 Access online Help.

2 **Search**.

A search field is displayed.



3 Type the word(s) that you want to locate.

4 **Search**.

If the word(s) you typed appears in the document, each instance where it appears will be shown.

Printing Help Information/Printing the Operator's Manual

The **Print Manual** feature of the online Help system allows you to print all or part of the Operator's Manual (Instructions For Use). This is the same information that is contained in the Help but in a printable book format.

---

1 **Help** ▸▸ **Print Manual**.

---

2 Locate the information you want to print.

---

3 **File** ▸▸ **Print**.

---

4 Define what pages you want to print. You can print all or part of the document.

---

5 **OK**.

5.6 USING YOUR AC•T 5diff CP HEMATOLOGY ANALYZER OPERATOR MANUALS CD-ROM

An Operator Manuals CD-ROM was shipped with your instrument and contains the following components:

- COULTER® AC•T™ 5diff CP Hematology Analyzer Instructions For Use (.PDF and .HTML files),
- COULTER® AC•T™ 5diff CP Hematology Analyzer Host Transmission Specification, English (.PDF file)
- Adobe® Acrobat® Reader 4.0 (or higher) for reading the .PDF files

The purpose of the CD-ROM is to allow you to access the same information from any compatible PC that you access through the Help menu on the AC•T™ 5diff CP Workstation PC.

You can use this CD-ROM at any PC that meets the requirements listed in Minimum System Requirements for Using the CD-ROM.

ATTENTION: The Workstation PC that is part of your laboratory's AC•T™ 5diff CP system is configured to work only with the AC•T™ 5diff CP system and is not intended for other PC operations, such as running other software applications, playing computer games, or accessing the Internet. **This means that you cannot read the contents of this CD-ROM on the AC•T™ 5diff CP system Workstation PC.** You must use a different PC.

Minimum System Requirements for Using the CD-ROM

DO NOT USE THE CD-ROM ON YOUR WORKSTATION PC.

You can use this CD-ROM on any PC that meets these *minimum* requirements:

- Microsoft® Internet Explorer 4.0 (or higher) for displaying the.HTML files
- An IBM® PC or compatible with a CD-ROM drive
- A Microsoft® operating system: Windows® 95, Windows 98, Windows 2000, Windows ME, or Windows NT® 4.0 (or higher)
- 32 MB RAM
- Display settings: 800x600 and 256 colors

Launching the Manual from the CD-ROM

The contents of the CD-ROM will not be installed on your PC. You will view and print directly from the CD-ROM.

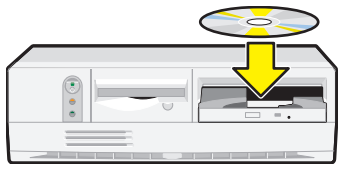
ATTENTION: If you cannot access the Operator's Guide on this CD-ROM, contact your Beckman Coulter Representative.

The contents of this CD-ROM will not automatically install on your PC.

1 Turn on your PC and allow it to boot up. Refer to the PC manual for instructions.

2 Insert the CD-ROM into the CD-ROM drive.

- If Autorun is enabled on your PC, the PC automatically launches the Operator's Guide.
- If Autorun is disabled on your PC, do steps 3 through 4.



3 Locate the **Start.HTM** file (*CD-ROM drive letter*:\Start.HTM):

a. the Windows **Start** button.

b. **Run**.

c. **Browse** and locate the CD-ROM drive.

d. Double-click the CD-ROM drive letter (usually **D** or **E**).

4 Double-click **Start.HTM** to launch the Operator's Guide.

5 Navigate through and/or print the manual as noted ***Heading 5.5, USING THE ONLINE HELP SYSTEM***.

5.7 SOFTWARE DETAILS

Overview

The Workstation software is based on Windows-NT. Familiarity with Windows conventions and use would be beneficial but is not required.

Initial Windows-NT Logon

When the software initially loads, a Windows-NT logon window appears. This is where you enter the user name and password information.

User Names and Passwords

When you log on to the system, you are required to type a user name. Type one of the following:

- BCI (for normal operation), or
- Admin (for special procedures).

For normal operation, which is the majority of the time, logon using BCI as the User name. 123 is the password for the BCI User name. Once you enter the password for BCI, the system automatically loads the Workstation application software.

For special procedures, logon using the Admin User name. Only do so when instructed by a Beckman Coulter representative, who will provide you with the Admin password at that time.

Operator ID Logon

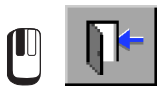
After the initial Windows-NT logon, a splash screen appears. This is where you enter your Operator ID.

Your Operator ID is a 3 character alphanumeric code that identifies you as the operator. Use your initials or any other 3-character combination that will distinguish you from other users.

This code is used for traceability purposes. For example, if a user with a code of LTS changes a reagent and updates the Reagent log, LTS will appear in the Reagent log as the user responsible for that action.

Change Operator ID

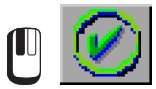
You do not have to log out completely to change Operator IDs.

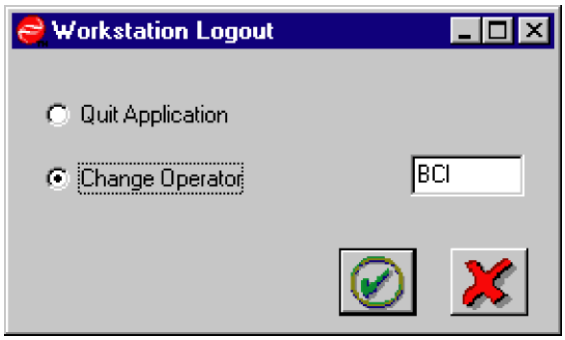
1  .

2 Change the Operator ID.

a. Select **Change Operator**.

b. Type the new Operator ID in the box.

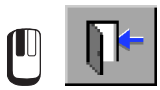
c. Press Enter or  .



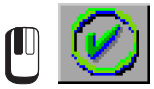
3 The next operator is now logged in with their Operator ID.

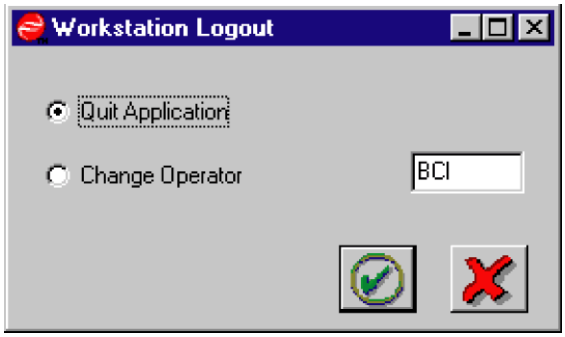
Logout

Do this procedure to log out and quit the application.

1  .

2 Select **Quit Application** then press Enter

or  .



Software Passwords

Various Workstation software areas, such as setup and calibration, require you to enter an "Administrator" password before permitting access. When the "Administrator" password is requested, type 123 to gain access to that particular software screen.

Other Workstation software areas, such as service diagnostics, requires you to enter a "Service" password before permitting access. The "Service" password is for use by Beckman Coulter representatives.

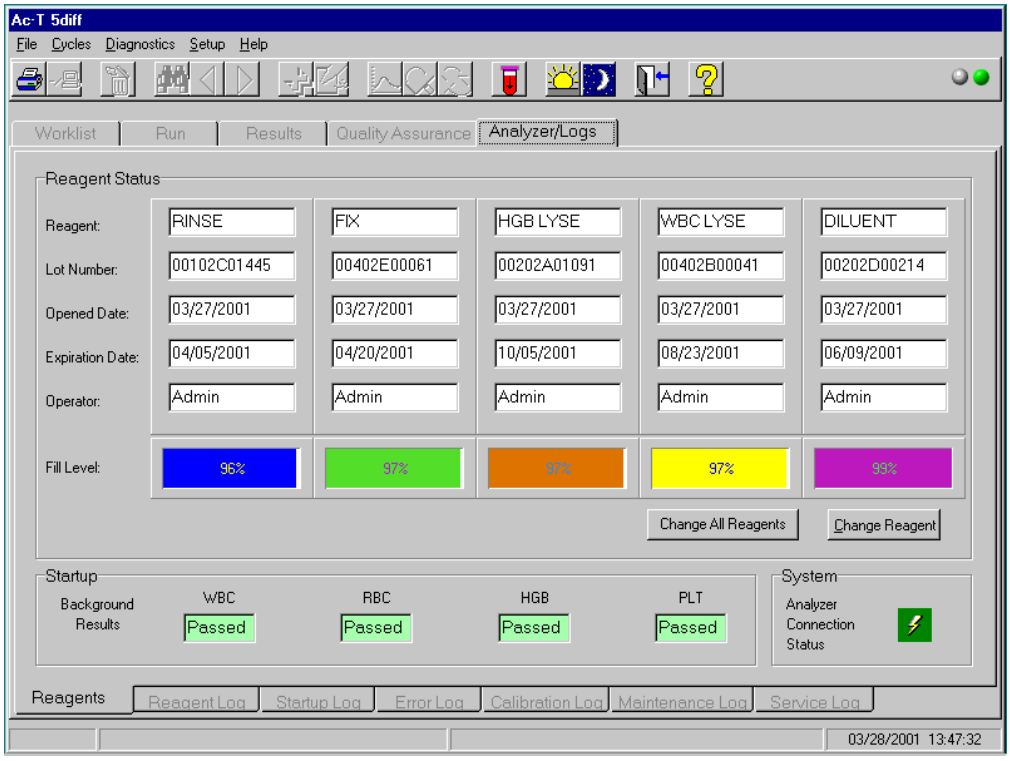
Primary Windows

The primary windows are those displayed after you select one of the following tabs:

- Worklist
- Run
- Results
- Quality Assurance
- Analyzer/Logs

After you log on, the Analyzer/Log window (Figure 5.2) appears.

Figure 5.2 Primary Window (Analyzer/Logs)



Each menu item offers additional software choices. For additional information, see ***Pull-down Menus***.

Menu Bar

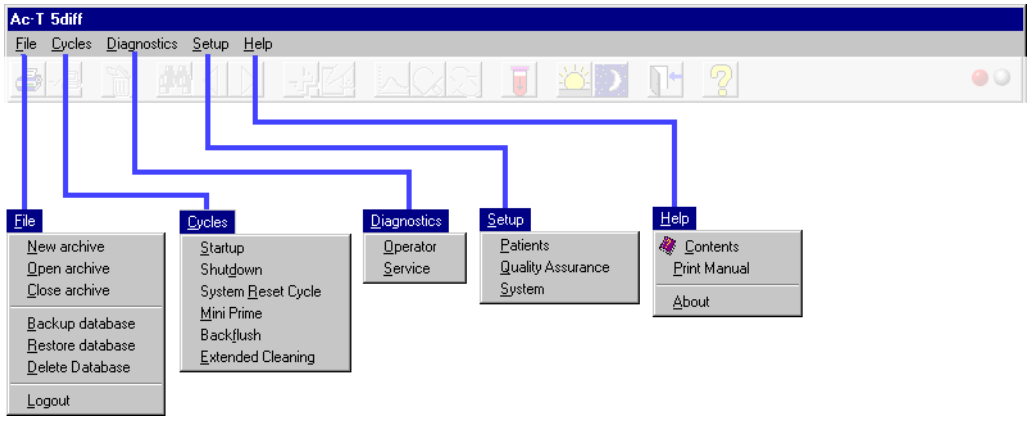
The menu bar, which appears across the top of a window, contains the pull-down text menus for the system's software. See Figure 5.3.

Figure 5.3 Menu Bar

Pull-down Menus

Figure 5.4 shows the software options available for each pull-down menu.

Figure 5.4 Pull-Down Menu Options



Tool Bar

A tool bar (Figure 5.5) appears below the menu bar and displays icons that, when selected, execute the function they represent. If an icon is grayed out, it is unavailable for use.

Figure 5.5 Tool Bar

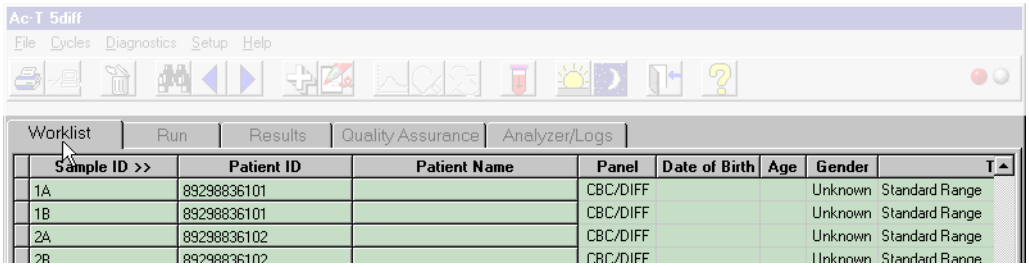
Note: The tool bar disappears if a secondary window is displayed via a menu selection, such as **Setup** and **Diagnostics**.

Tabs

Tabs appear at the top or bottom of a window and group information related to that window. For example, Worklist information is grouped in the window viewable by selecting the **Worklist** tab (Figure 5.6.)

The tab text is gray when the tab is not selected and black when selected.

Figure 5.6 Worklist Tab



Buttons

There are three types of buttons used within this software:

- command (text) buttons,
- bitmap buttons, and
- radio buttons.

Command Buttons

Command buttons contain text and appear within various windows of this software. These buttons execute functions when selected. See Figure 5.7.

Figure 5.7 Text Button

Bitmap Buttons

Bitmap buttons, which function the same as command buttons, appear in popup windows and, for common functions, appear across the bottom of Setup and Diagnostic screens. See Figure 5.8.

Figure 5.8 Bitmap Button: Drop-down Box

Radio Buttons

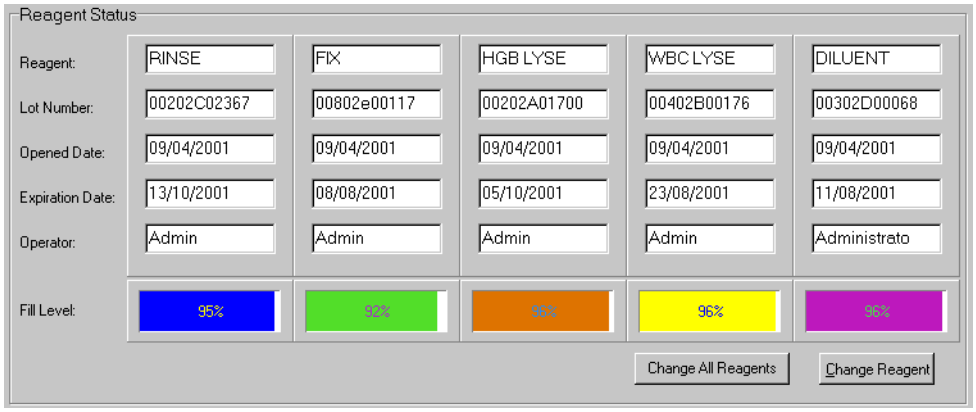
Radio buttons, which appear within various windows of this software, allow you to choose one of the options presented. See Figure 5.9.

Figure 5.9 Radio Buttons

Fields (Text Boxes)

Fields, which appear within various windows of this software, are rectangular areas where you can input or display information. See Figure 5.10.

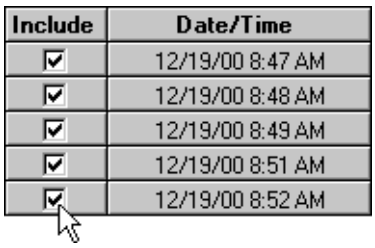
Figure 5.10 Fields



Check Boxes

Check boxes, which appear within various windows of this software, allow you to select (include) or deselect (exclude) options. See Figure 5.11.

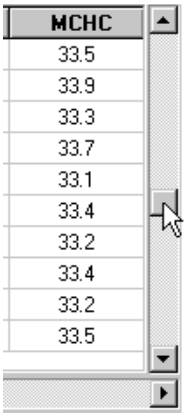
Figure 5.11 Boxes



Scrollable Lists

Scrollable lists are lists of information that require you to scroll to see all available entries. See Figure 5.12.

Figure 5.12 Scrollable List



5.8 WORKING WITH THE SOFTWARE

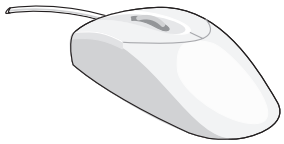
When working with the instrument's software, be sure you understand the basics of:

- ***Using the Mouse***,
- ***Moving the Cursor***,
- ***Selecting Menu Items***,
- ***Scrolling***,
- ***Editing Text***,
- ***Saving Changes***, and
- ***Selecting/Deselecting Software Fields***.

Using the Mouse

A mouse (Figure 5.13) is connected to your Workstation and allows you to navigate through the software and to select certain software functions.

Figure 5.13 Mouse



Throughout this manual, you will be instructed to select a software option by "clicking" on it with the mouse. Do this procedure to learn how.

---

1 Place the cursor over the item you want to select.

---

2 Click (press and release) the left mouse button.

Note: If the selection is not made, try again; check the connection if necessary. If the problem persists, contact a Beckman Coulter representative.

Moving the Cursor

To move the software cursor, move the mouse or press Tab.

Selecting Menu Items

There are two ways to select a menu item as defined below.

1 the item.

OR

2 Press Alt and simultaneously press the underlined letter of the menu item.

For example, to select File, press Alt + F and release both keys after the menu item is selected.

3 Once a pull-down menu is open:

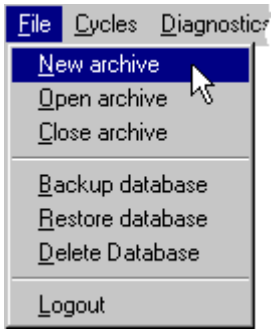
- You can press ↑ or ↓ to highlight a menu option then press Enter to select it.

OR

- Press the underlined letter of the menu item.

OR

- the item.



Scrolling

Some windows contain information that cannot be viewed all at once on the screen. For those windows, horizontal and/or vertical scroll bars are available to allow you to scroll across or up and down the window. See Figure 5.14.

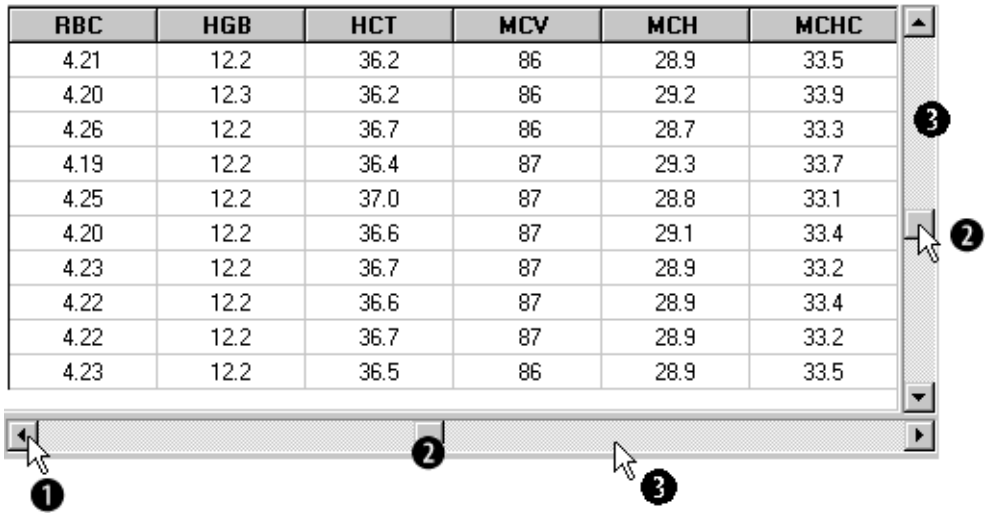
To scroll, do **one** of the following:

❶ the cursor on one of the arrows to scroll the window in the direction of the arrow.

❷ and hold the slider box and drag it along the scroll bar.

❸ the slider instead of dragging the slider box.

Figure 5.14 Scroll Bars



Editing Text

There may be times when you need to edit text.

---

1 Move the cursor to the line of text where you want to delete information.

---

2 the left mouse button to anchor the cursor.

3 Edit the text.

4 Save the changes. See ***Saving Changes*** for details.

Saving Changes

Throughout the procedures, you will be instructed to save information. There are two save icons on your system.

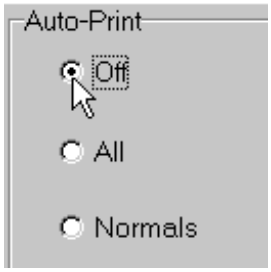
Saves the information and exits the screen.

Saves the information and remains at the current screen, allowing you to continue working at that screen.

Selecting/Deselecting Software Fields

Some software screens allow you to select (activate) or de-select (deactivate) certain software features.

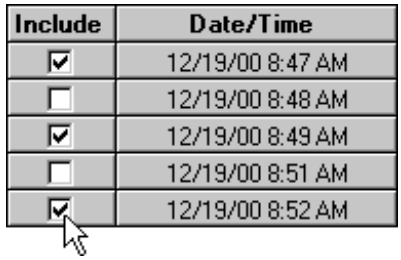
1 Move the cursor to the desired radio button or check box.



2 For check boxes, the check box to select/deselect the corresponding feature:

☑ = selected.

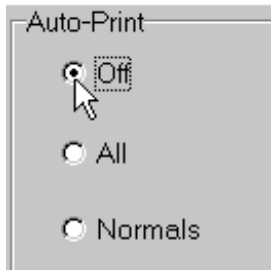
☐ = not selected.



3 For radio buttons, a button to select/deselect the corresponding feature.

◉ = selected

○ = not selected

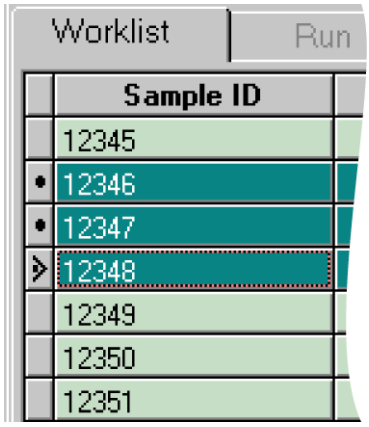


4 To select from a list:

a. Press the Ctrl key and on each row you want to select.

b. Verify that a black dot

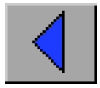
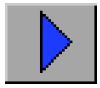
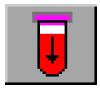
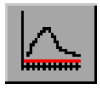
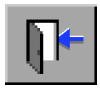
or appears in the far left column and that the entire row is highlighted.



5.9 SYSTEM ICONS

Icons depict executable functions or status information. Table 5.1 shows the icons used on this system.

Table 5.1 Software Icons

Print	Transmit to Host	Delete	Find	 Previous	 Next	Restore Default
Add	Edit	Validate	Re-run	 Load Sample	Help	 Results/List
Startup	Shutdown	Analyzer Connected	Analyzer Disconnected	Save/Exit	Save/Remain	Cancel
 Logout/Exit						

5.10 PRINTING

Overview

The first print job after initial Startup takes a few seconds to print. Subsequent print jobs print without delay.

There are several ways to print information. On most of the screens, appears at the bottom of the window. By selecting that icon, only the information pertaining to the open window prints.

also appears in the tool bar. This particular printer icon does not print the information pertaining to the open window. However, it provides general printing options for the primary windows: Worklist, Run, Results, Quality Assurance, and Analyzer/Logs. This means, for example, that you can print information from the Worklist without having to be in the Worklist screen. For details, see ***Printing Using the Printer in the Tool Bar (Primary Windows Only)***.

Printing Using the Printer in the Tool Bar (Primary Windows Only)

Primary window (Worklist, Run, Results, Quality Assurance, and Analyzer/Logs) information can be printed by using in the tool bar.

Note: Empty logs (Reagent, Startup, Error, and so forth) do not print because there is no information in them.

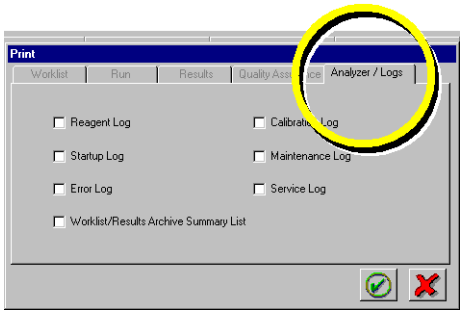
---

1 in the tool bar from any primary window.

---

2 the desired tab to select the item(s) you want to print.

For example, if you want to print a Reagent Log, **Analyzer/Logs** for options.

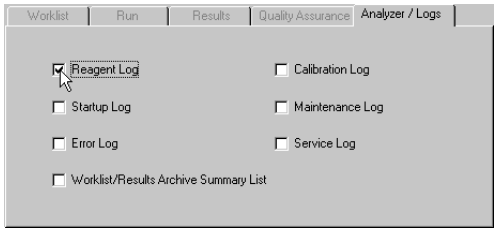


---

3 the items you want to print.

For our example from above,

Reagent Log.



---

4 .

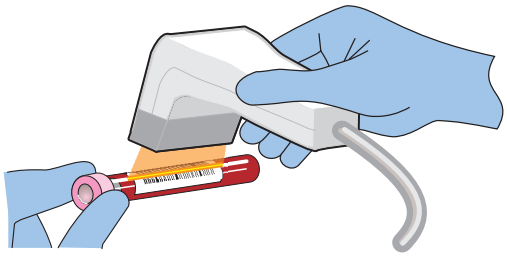
5.11 ENTERING INFORMATION USING THE BARCODE SCANNER

1 the field where you want to enter information.

For example, if you want to scan the Sample ID, the Sample ID field.

2 Position the barcode reader over the barcode label and squeeze the trigger button.

If the barcode label was successfully read, the barcode reader beeps, the LED illuminates on the reader, and the cursor advances to the next field.



3 Verify that the information was placed in the correct field.

5.12 UNDERSTANDING HOW FLAGGING SETS ARE APPLIED

Your system includes 6 pre-defined flagging sets Table 5.2.

Table 5.2 Pre-Defined Flagging Sets

Flagging Set Number/Name	Age Range
1. Standard Range	–
2. Man	> 12 years
3. Woman	> 12 years
4. Newborn	0 to <= 30 days
5. Infant	1 month to < 6 years
6. Child	>= 6 years to <= 12 years

– No defined range

IMPORTANT Due to the system's calculation methods for determining the age from the date of birth, the precision of the age calculation is limited to +/- one day. When the age is close to the limit of a flagging range, the adjoining flagging range may be selected.

You can add up to 14 additional flagging sets (numbers 7 through 20) and define the name and other parameters. See ***Creating Additional Flagging Sets***. If a result is outside the selected range, the result will be flagged:

You can choose any flagging set to be the default flagging set. When your instrument is installed, Standard Range is established as the default flagging set. However, you can change the default flagging set to meet your laboratory's needs. See ***Selecting a Default Flagging Set***.

You can edit the patient limit ranges and action limit ranges for existing flagging sets, except 'Standard'.

If a result is outside the **patient limit range**, the result will be flagged:

- *H* for results above the upper limit, and
- *L* for results below the lower limit.

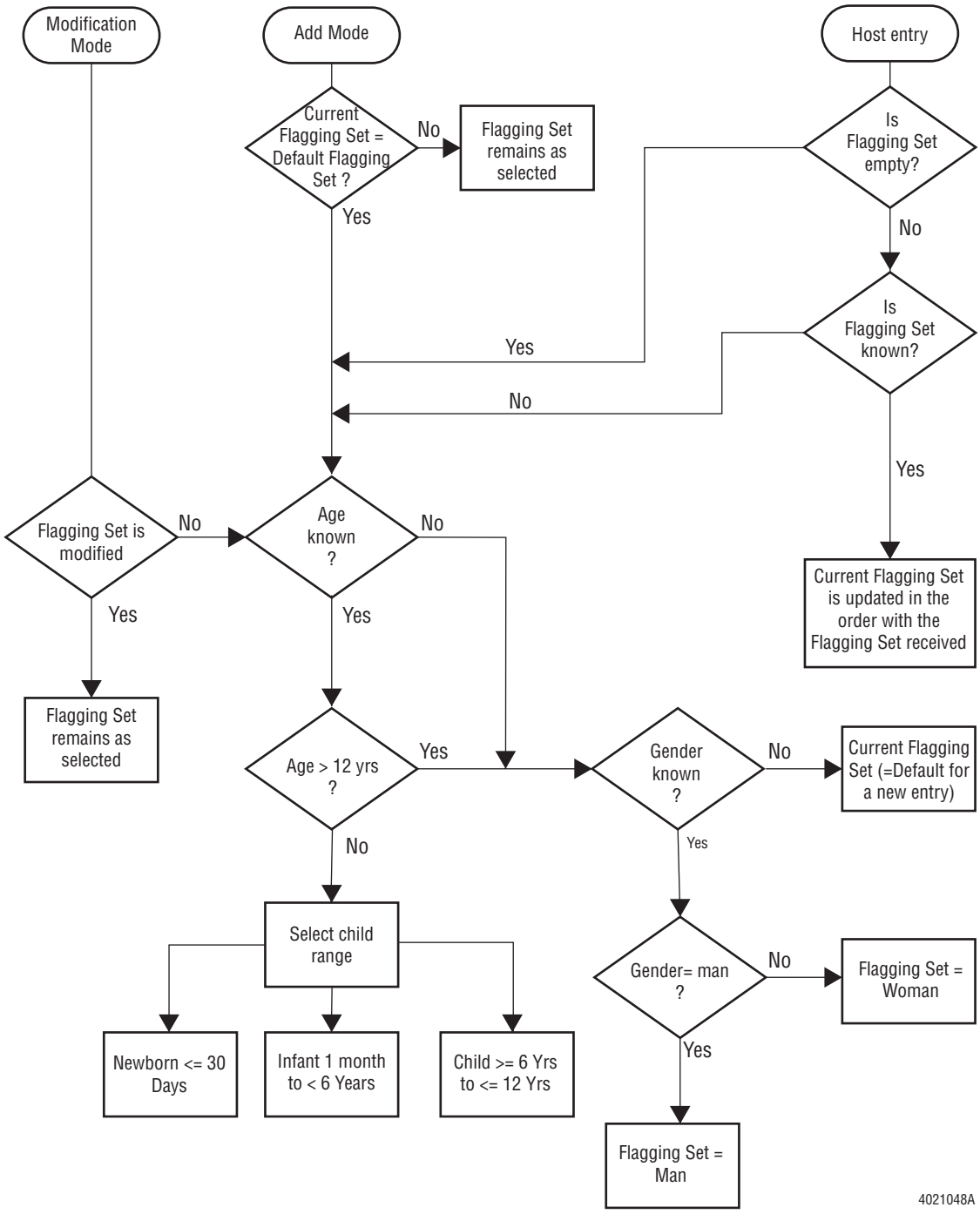
See ***Editing Patient Limit Ranges in a Flagging Set*** for additional information.

If a result is outside the **action limit range**, the result will be flagged:

- *HH* for results above the upper limit, and
- *LL* for results below the lower limit.

Figure 5.15 shows the flagging set hierarchy that defines how flagging sets are applied to Sample IDs.

Figure 5.15 Flagging Set Hierarchy



5.13 USING WORKLISTS

Overview

A Worklist contains sample and patient identification information for samples that are pending analysis. Before the sample is analyzed, you can enter/edit patient demographics, which will be saved with the sample. Demographics include patient name, age, date of birth, gender, clinic location, physician, and comments. Information downloaded from a host computer cannot be edited.

All patient information is printed on the final report and transmitted to the host computer, if applicable.

The Workstation matches sample results with the additional information entered based on sample ID. The Worklist entry is removed upon analysis when the workstation has matched the results to the pre-assigned data.

You can add demographic information:

- by manually entering the information (see ***Adding Entries To (Creating) a Worklist***), or
- by downloading the information from a host computer (see ***Downloading Worklists from a Host Computer***).

Once the information is present on the Worklist, it will be added to the sample results when the system matches the Sample ID of the added information with the Sample ID of the processed sample.

The Worklist displays a listing of all samples that have had additional information entered into the system but have not been processed. Once a sample that has matching information on the Worklist has been processed, the Worklist entry is removed. The results are now available on the Results screen and the Run screen.

Note: The duplicate sample ID check is a function of the Worklist. This process occurs for all samples and is independent of the process of adding patient information.

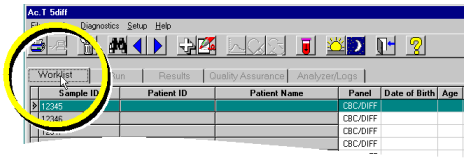
Adding Entries To (Creating) a Worklist

Do this procedure if you want to add entries to a Worklist. When entering information, remember:

- A Sample ID is required; the remaining information is optional.
- The Patient ID field accepts the ID from a list or an ID that is manually entered.
- The Patient name field accepts alphanumeric characters.
- If the date of birth is not known, enter the patient's age.

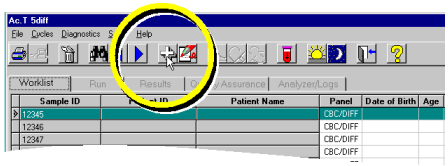
---

1 the **Worklist** tab.



---

2 .

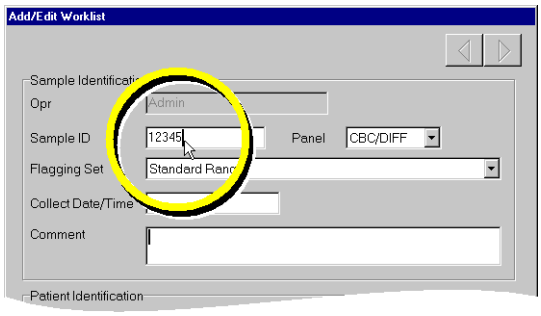


---

3 Enter the Sample ID (up to 16 alphanumeric characters and no spaces) by manually entering the ID or by scanning the barcode, if applicable.

Note: If you try to enter more than 16 characters, an audible alarm sounds.

ATTENTION: Sample analysis will not occur without a valid Sample ID.



---

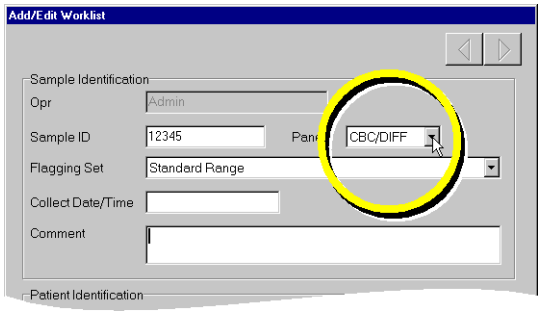
4 Press Tab to move the cursor to the Panel field.

5 Select the panel – **CBC** or **CBC/DIFF**:

a. .

b. Select **CBC** or **CBC/DIFF**.

c. Press Tab to move the cursor to the Flagging Set field.



6 Select the flagging set:

a. .

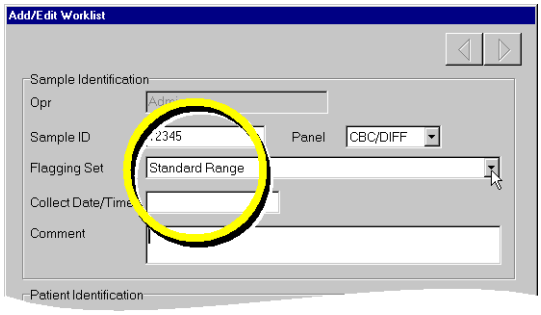
b. Select the desired flagging set.

c. Press Tab to move the cursor to the Collection Date and Time field.

If you manually select a flagging set, that flagging set will be applied.

If you do not enter the patient's birth date and gender, the default flagging set is used.

For additional information on the flagging set hierarchy, see Figure 5.15.

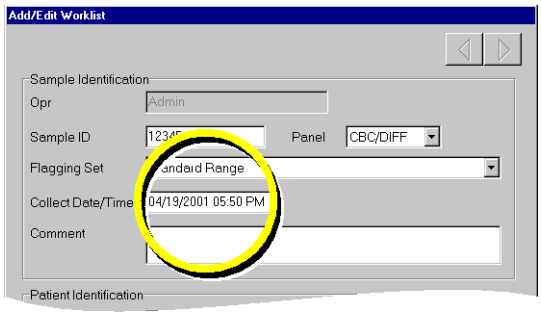


7 Enter the date and time that the specimen was collected:

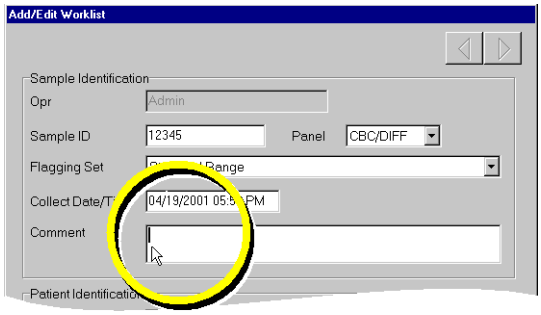
a. Enter the complete date.

b. Enter the time.

c. Press Tab to move the cursor to the Comments field.

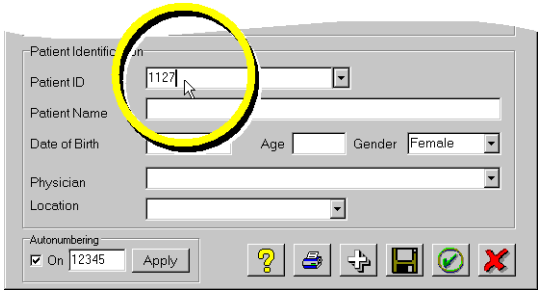


8 Type your comments (up to 50 alphanumeric characters and spaces), and press Tab to move to the Patient ID field.



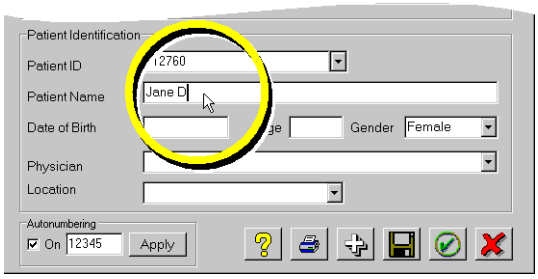
9 Enter the Patient ID (up to 25 alphanumeric characters and no spaces):

- manually type the Patient ID, or
- scan the Patient ID from the barcode, if applicable, or
- and select the Patient ID from the existing list of Patient IDs, if applicable.

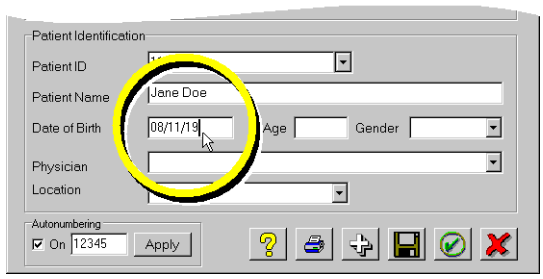


10 Press Tab to move to the Patient Name field.

11 Enter the patient's name (up to 30 alphanumeric characters and spaces) and press Tab to move to the date of birth field.



12 Enter the patient's date of birth and press Tab.



The system automatically calculates the patient's age and populates the age field based on the date of birth you entered.

> **Note:** If you do not enter the year, an *invalid date* message appears.

If you prefer to enter the age rather than the date of birth, use the following designators. They must be lower case.

d = day

w = week

m = month

y = year

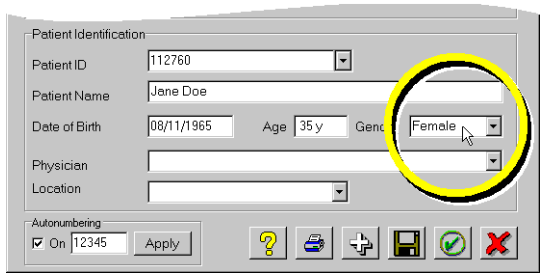
13 Press Tab Tab to move to the patient's gender field.

14 Select the patient's gender:

a. .

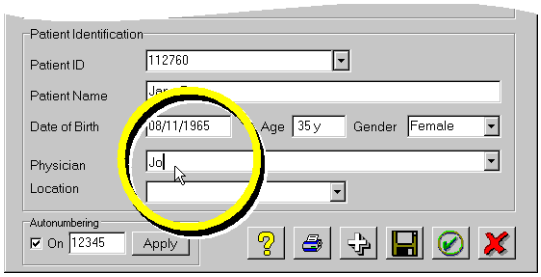
b. Select the gender.

c. Press Tab to move the cursor to the physician's name field.



15 Enter the physician's name (up to 30 alphanumeric characters and spaces):

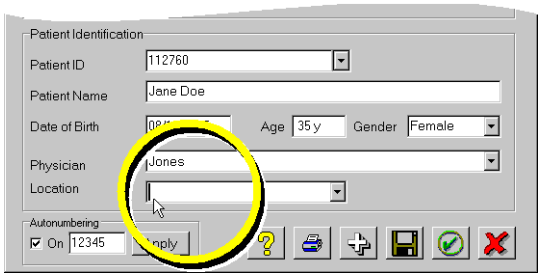
- manually enter the physician's name, or
- and select the physician from the list, if applicable.



16 Press Tab to move the cursor to the Location field.

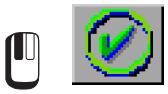
17 Enter the patient's location (up to 15 alphanumeric characters and spaces):

- manually enter the location, or
- and select the location from the existing list of locations, if applicable.



18 Save the information:

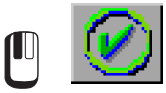
- If you have finished adding

  Worklist entries,  to save the information and exit the window.
- If you want to continue adding

  Worklist entries, to save the infomration and remain at the window.
- If you want to exit the window **without saving** the information,

  .

19 When you finish adding entries,

 to save and close the Worklist.

Downloading Worklists from a Host Computer

If the host transmission protocol is established, demographics are automatically downloaded from the host computer.

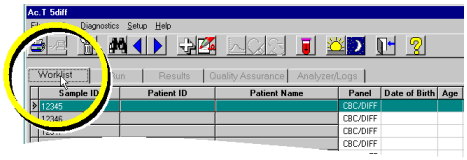
You cannot edit any information downloaded from the host computer.

Editing Worklist Entries

ATTENTION: Results cannot be edited and demographics downloaded from the host computer cannot be edited.

Do this procedure to edit a Worklist entry.

1 Select the Sample ID or the Patient ID for the patient demographics you want to edit.



a. the **Worklist** tab.

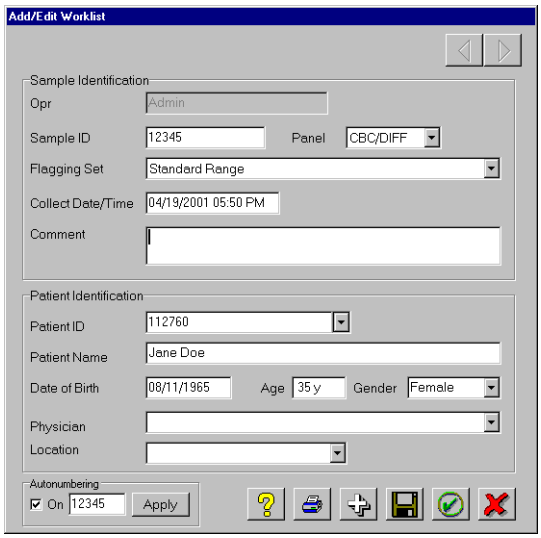
b. Highlight the desired entry.

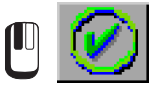
2 .

3 Edit the demographics.

ATTENTION: The system selects the flagging set based on the age and gender of the patient. If you do not enter an age and the gender and do not select a flagging set, the default flagging set will be selected automatically.

You can manually enter the information, or if the database has the information (doctor, location, etc.), select it via drop-down box.



4  to save and exit the screen.

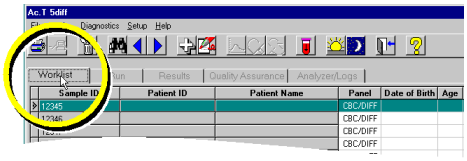
Deleting Worklist Entries

Do this procedure if you want to delete an entry from the Worklist.

ATTENTION: If you delete a Worklist entry for a new Patient ID, any entered demographic information will be deleted. If the entry has a Patient ID already in the system prior to this Worklist entry, then the demographic information for this Patient ID on the Worklist (not in the database) will be deleted when you delete the entry.

---

1 the **Worklist** tab.

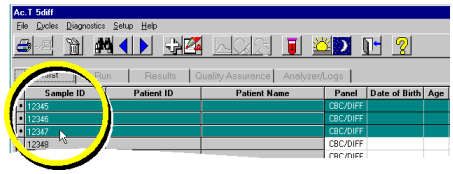


---

2 Highlight the item you want to delete.

To select multiple entries for deletion:

1) Press the Ctrl key and each entry you want to delete.
2) Verify that a black dot appears next to each selected entry.



---

3 .

---

4 **OK** to delete the selected item(s).

6.1 STARTUP

IMPORTANT Do not log out of the Workstation while the Analyzer is running a cycle. Logging out during an Analyzer cycle will cause problems with the Analyzer/Workstation communication.

Startup automatically runs when the instrument is powered on if the automatic Startup feature is enabled.

If the background counts are not within acceptable limits after the first Startup cycle, the instrument automatically performs Startup up to two more times. If Startup fails after the third attempt, a *STARTUP FAILED* message appears on the screen and on the report.

Background limits are fixed and cannot be changed. The acceptable background limits are:

WBC ≤ 0.3 x $10^3/\mu L^3$
RBC ≤ 0.03 x $10^6/\mu L^3$
Hgb ≤ 0.3 g/dL
Plt ≤ 7.0 x $10^3/\mu L^3$

If the system determines that there is insufficient reagent to complete the day's work, *Reagent(s) Low. Insufficient Reagent to Complete The Daily Workload* appears.

- Identify the low reagent and change it according to the ***Changing Reagents***.

  OR

- Continue and change the reagent when the specific reagent low message is displayed.

Do this procedure if you want to run Startup again. The Startup cycle runs for approximately 3 minutes.

IMPORTANT Do not log out of the Workstation while the Analyzer is running a cycle. Logging out during an Analyzer cycle will cause problems with the Analyzer/Workstation communication.

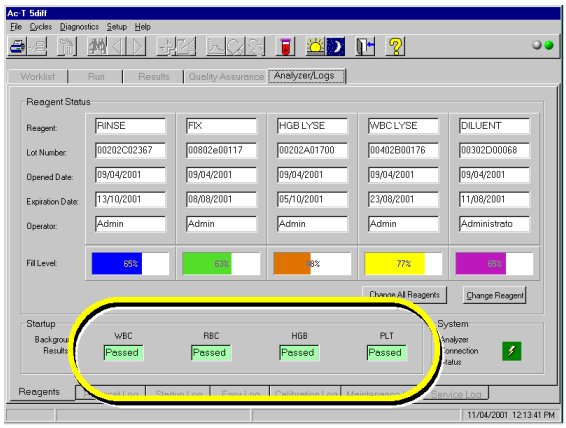
---

1 If automatic Startup at power up is

disabled, or **Cycles ▸▸ Startup**.

When Startup begins, the Analyzer/Logs screen automatically appears. After about 3 minutes, Startup will be completed. The status will be displayed on the Analyzer/Log screen and results will be stored in the Startup Log.

2 Review the Startup results status:

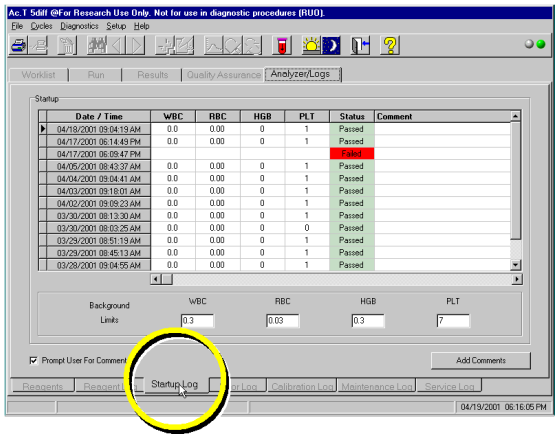


a. **Analyzer/Logs** if the screen is not already displayed.

b. Review the Startup results:

- If *Passed* appears, go to step 4.
- If *Failed* appears, go to step 3.

3 If *Failed* appears on any Startup result:



a. **Startup Log** tab and evaluate the numeric results.

b. or **Cycles** ▸▸ **Startup** to initiate another Startup routine.

c. If the Startup continues to fail, contact a Beckman Coulter representative.

Note: the **Run** tab to view the Startup results.

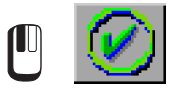
4 The Startup log automatically prints (in tabular format) if Auto-Print is enabled.

If Auto-Print is disabled:

a. .

b. Verify that the Analyzer/Logs tab is selected.

c. **Startup Log**.

d.  .

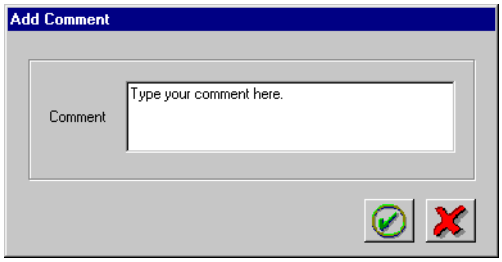
Note: The Startup log maintains the most recent 50 entries.

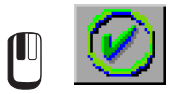
5 Add comments to the Startup log, if desired:

a. If the **Add Comments** box appeared automatically, type your comments.

To access the **Add Comments** box,

Startup Log tab ▸▸ **Add Comments** button then type your comments.



b.  to save your comments.

6.2 WASTE CONTAINER LEVEL CHECK

At the beginning of each day, check the waste container to determine if it needs to be replaced. If so, do ***Replacing the Waste Container***.

6.3 PRINTER CHECK

At the beginning of each day (or shift), be sure the printer is ready to print.

---

1 Be sure there is an adequate paper supply in the printer.

- If so, go to step 2.
- If not, add paper according to the printer's user manual.

---

2 Turn the printer on.

---

3 Be sure the printer is ready. See your printer manual for details.

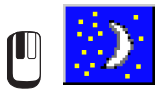
6.4 SHUTDOWN

At the end of each day, do this procedure to

- cleanse the instrument,
- shut down the computer,
- and power off the analyzer and PC.

IMPORTANT Do not log out of the Workstation while the Analyzer is running a cycle. Logging out during an Analyzer cycle will cause problems with the Analyzer/Workstation communication.

---

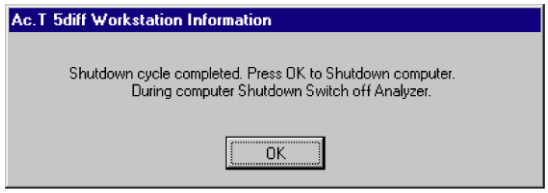
1  .

The instrument cycles Rinse reagent for cleaning and goes into a stand-by mode.

The Reagent window is displayed during Shutdown.

---

2 When Shutdown is complete a message box appears.


Ac.T 5diff Workstation Information
Shutdown cycle completed. Press OK to Shutdown computer.
During computer Shutdown Switch off Analyzer.
OK

a. **OK** to shut down the computer.

b. Turn off the Analyzer power switch.

c. Wait for the "*It is now safe to turn off computer*" message to appear.

d. Turn off the PC power switch.

CAUTION Wait at least 30 seconds before performing the ***Power Up*** and ***Log On*** procedures.

IMPORTANT After doing Shutdown, you must do a ***Power Up*** and ***Startup*** before operating the instrument again.

7.1 RUNNING CELL CONTROLS

Do this procedure before analyzing patient samples to ensure that the system is within acceptable operating limits. Beckman Coulter recommends that you analyze three levels (low, normal, and high) of cell control material.

The cell control for the A^C•T 5diff CP hematology analyzer is A^C•T 5diff Control Plus. For information on setting up controls, see ***Setting Up a Control File - Upload from Control Disk***.

When the system analyzes the A^C•T 5diff Control Plus control, it processes the control in the same manner as a patient sample. The neutrophil, lymphocyte, monocyte, and eosinophil populations are derived from the flow cell. The basophil population is derived from the WBC/BASO bath.

The Workstation allows you to set up files to store control results for CBC and/or CBC/DIFF analysis. Before you can store controls results in a file, the file must be setup for the appropriate information, such as control name, Sample (Lot #) ID, assay values, expected ranges, and so forth. For control material details, refer to the package insert.

Note: You cannot preassign controls into the Worklist.

IMPORTANT Risk of erroneous results. Do not analyze an expired control. Always verify the control's expiration date including open vial stability before analysis.

1 Enter the control ID in the Sample ID field:

- Manually type the reserved lot number for the control as the Sample ID at the Run screen:

  1) the **Run** tab.

  2) Type the reserved lot number for the control in the Sample ID Next field.

OR

- Open the appropriate control file:

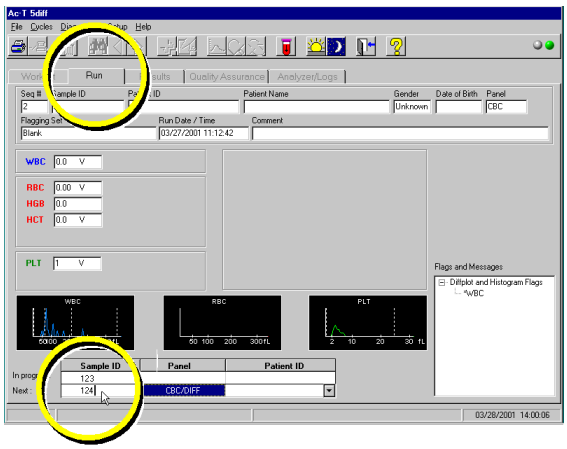
  3) the **Quality Assurance** tab.

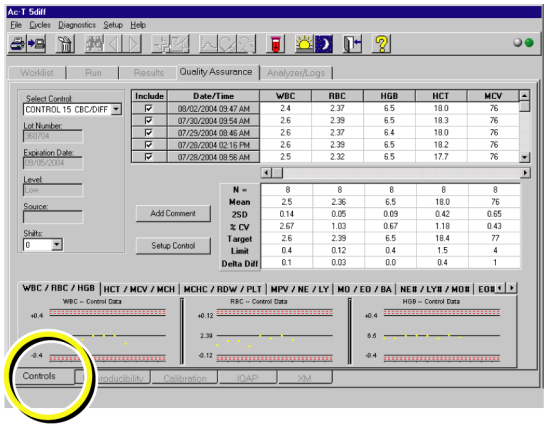
  4) the **Control** tab.

  5) Select the desired control file.

     a) at Select Control.

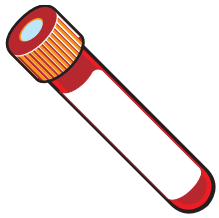
     b) the desired control.





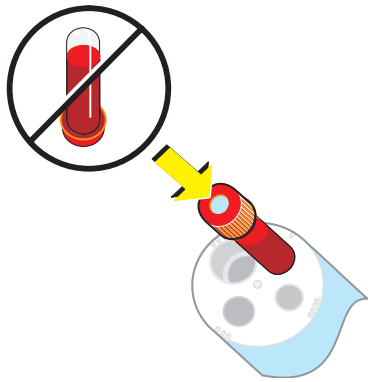
IMPORTANT Risk of erroneous results if the control is not mixed according to the instructions in the control's package insert.

2 Mix each control vial according to the instructions in the A^{C}•T 5diff Control Plus cell control package insert.



3 Inspect the vial's contents to ensure that all cells are uniformly distributed and that there is no evidence of deterioration.

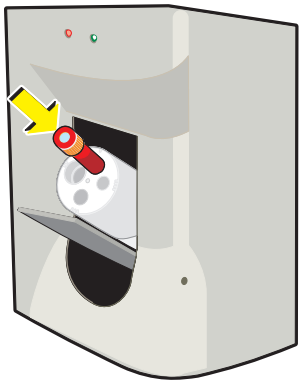
IMPORTANT Risk of erroneous results and/or instrument damage if tubes/vials with hard caps are processed with the caps on. Always remove hard caps from tubes/vials before processing.



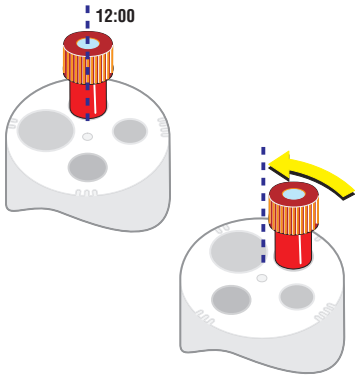
4 Insert the tube/vial correctly into:

- slot #1 of Tube Holder #1, or
- slot #4 of Tube Holder #2.

For information about the correct slot for each tube/vial, see Table D.1.



IMPORTANT Risk of erroneous results if the desired sample tube/vial is not positioned in the pierce position (12 o'clock) in the Analyzer.



5 Ensure that the tube is in the pierce position within the tube holder.

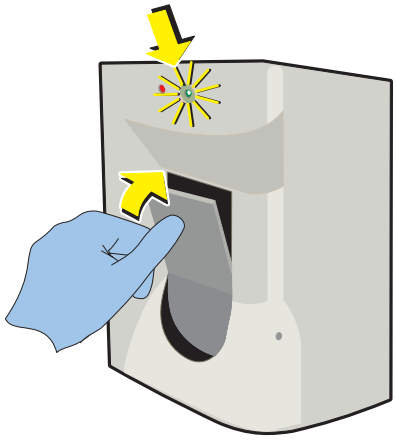
- If the tube is in the pierce position (12:00 o'clock) within the holder, do step 6.
- If the tube is not in the pierce position within the holder, rotate the holder until the tube is in the pierce position.

IMPORTANT Do not log out of the Workstation while the Analyzer is running a cycle. Logging out during an Analyzer cycle will cause problems with the Analyzer/Workstation communication.

6 Close the tube holder door.

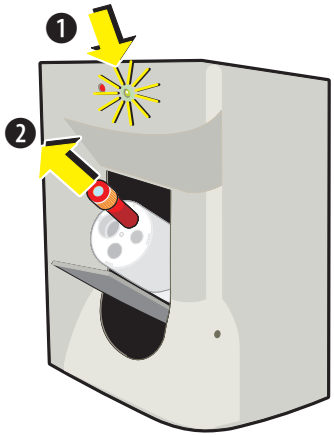
The red and green LEDs flash:

- When the red LED remains illuminated, the system is busy analyzing the sample.
- When the green LED remains illuminated, the instrument is ready for the next analysis.



7 When the LED is green (❶) and the tube holder door opens (❷), remove the tube/vial.

If the control lot number has been set up as "reserved," the Workstation identifies the sample as a control and places the results in the appropriate control file based on information entered in the Sample ID field.



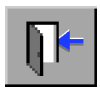
8 Repeat steps 1 through 7 for the remaining cell control levels.

Note: If you run an expired control the system displays a message to alert you but accepts the results. Be sure to remove these invalid results from the control file; if not immediately then before IQAP download.

9 Review the control results to ensure they are within the acceptable ranges before analyzing patient samples.

- Verify that none of the controls were run past their expiration date. If they were, remove the invalid results from the control file and run a control that is not expired.
- If the control results are within the acceptable ranges, you are ready to analyze patient samples.
- If a parameter value is out of range, the result is backlit in yellow and flagged with *H* or *L* on the Run screen. Review the control data according to your laboratory protocol or go to step 10.

  You can also:

  1) the **Quality Assurance** tab.
  2) Select the appropriate file from the Select Control drop-down box.
  3) Review the control file summary data. Scroll through the control runs as needed to view all data.
  4) To review the Levey-Jennings graphs, select the appropriate tab (scroll to the right, if necessary) and double-click the graph to expand the view. To close the graph when finished,  .

10 When control results are not within the acceptable ranges:

a. Ensure proper mixing and control material integrity, then rerun the control.

If results are still outside the acceptable ranges, do step b.

b. Analyze a new cell control vial. If the results are still outside the acceptable ranges, do step c.

c. Clean the system (see ***Diluter System***) and rerun the control.

d. Review the results:

- If the results are still outside the acceptable ranges, contact a Beckman Coulter representative.

  An out of range control result will appear with an *H* or *L* flag.
- If results are within the acceptable ranges, you are ready to analyze patient samples.

IMPORTANT Risk of failure to print and/or transmit all requested results. Do not delete result(s) until printing and/or transmitting are complete. Allow all results to complete printing and/or transmitting before using the delete function.

11 The control file results automatically print if Auto-Print is enabled.

If Auto-Print is disabled:

a. .

b. Select the print option.

c. .

IMPORTANT Risk of failure to print and/or transmit all requested results. Do not delete result(s) until printing and/or transmitting are complete. Allow all results to complete printing and/or transmitting before using the delete function.

12 The control file results automatically transmit if the Auto-Transmission option for control results is set to On.

If Auto-Transmit is set to Off:

a. Verify that the Include box is checked for each result you want to transmit.

b. .

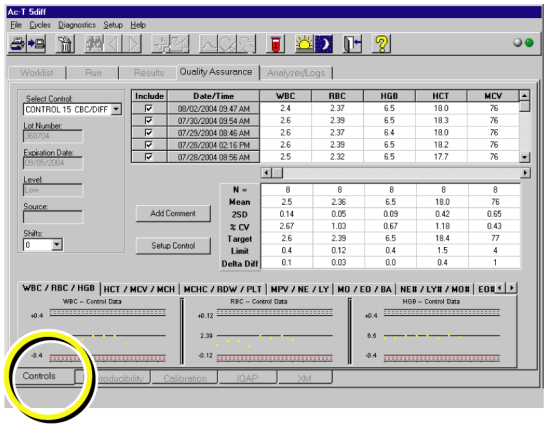
Note: To determine whether Auto-Transmit is set to On or Off for control results, see ***Defining Results Autotransmission Settings***.

Displaying Levey-Jennings Control Graphs

Do this procedure to display the Levey-Jennings Control Graphs.

1 the **Quality Assurance** tab.

2 the **Controls** tab.


Ac·T 5diff
File Cycles Diagnostics Setup Help
Worklist Run Results Quality Assurance Analyzer/Logs
Select Control:
CONTROL 15 CBC/DIFF
Lot Number:
Expiration Date:
Level:
Source:
Shift:
Add Comment
Setup Control
Include Date/Time WBC RBC HGB HCT MCV
N = Mean 2SD %CV Target Limit Delta Diff
WBC / RBC / HGB HCT / MCV / MCH MCHC / RDW / PLT MPV / NE / LY MO / EO / BA NEB / LYB / MOB EOB
Controls
Reproducibility Calibration IQAP XM

3 Select the control file to be reviewed:

a. at Select Control.

b. the desired control.

4 the tab that represents the Levey-Jennings control graph that you want to see. The 10 most recent control runs will be displayed.

To view all runs, double-click the graph.

The **WBC/RBC/HGB** tab is the default displayed. You may need to scroll to the right to see the tab you want.

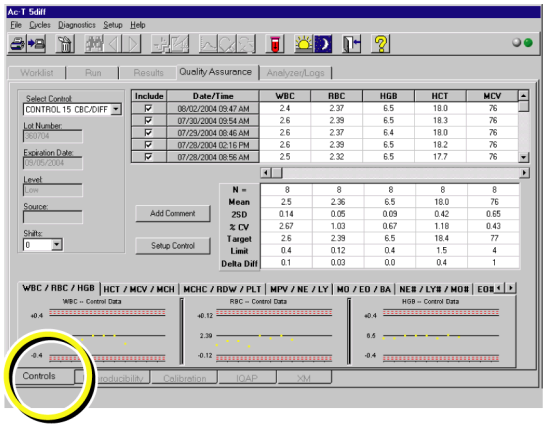
5 on the graph to close the graph view.

Adding QC Result Comments

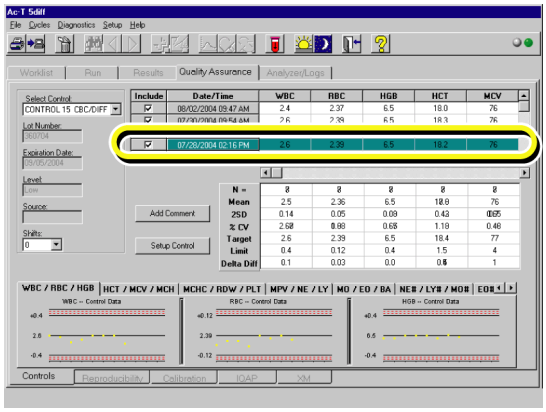
Do this procedure to add comments to control results.

1 the **Quality Assurance** tab.

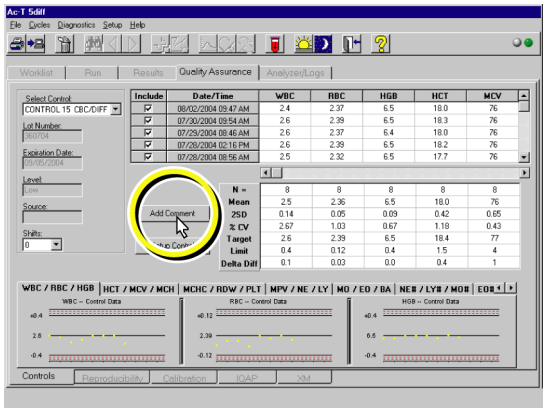
2 the **Controls** tab.



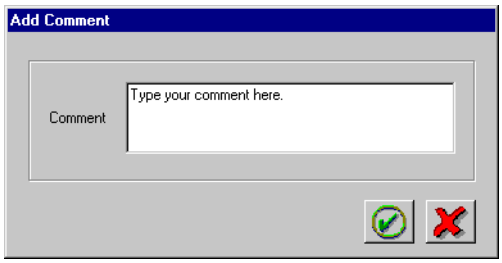
3 Highlight the row of the control result that requires comments.



4 Add Comment .



5 Type the comment.
(50 characters max.)



6 .

7.2 SUBMITTING CONTROL RESULTS FOR IQAP (INTERLABORATORY QUALITY ASSURANCE PROGRAM)

You can submit your control results to Beckman Coulter for inclusion in Beckman Coulter's IQAP program. The primary method for submitting control data from the A^{C}•T 5diff Cap Pierce instrument is a download to diskette (software version 2.00 or higher). As a backup, or for instruments with software versions below 2.00, summary data can be transcribed onto Intelligent Character Recognition (ICR) forms. The procedure for downloading to diskette is provided below. Refer to the IQAP Hematology Procedure Manual, PN 4206266, for the ICR forms procedure.

After enrolling in the IQAP, you will receive the necessary supplies and instructions for submitting data. Submit your IQAP data to Beckman Coulter each month immediately after completing your last set of controls.

For additional information, see ***IQAP (Interlaboratory Quality Assurance Program)*** in Chapter 1.

Note: The IQAP is unable to provide statistical comparison for parameters that do not have assay values assigned.

ATTENTION: Until you receive an IQAP report from Beckman Coulter for a particular set of data, do not delete that data. There may be times when you need to provide additional information for the IQAP report and, in those instances, you need to refer to the control data.

Preparing for IQAP Download

Do this procedure to prepare for downloading (saving) your cell control results to diskette for IQAP use. After you do this procedure, do ***Downloading Results to Diskette for IQAP Submission.***

---

1 Verify that the correct IQAP ID number is entered in the Workstation. See ***Setting Up the IQAP ID*** for the procedure.

ATTENTION: Incorrect runs will misrepresent the true mean and standard deviation (SD) of the summary data. Therefore, be sure that the runs you submit are correct.

2 Review each control file to verify that the data you are going to submit is correct.

If necessary, deselect any data runs that are not intended for IQAP submission, such as

- a control that was analyzed in the wrong file.
- control results with non-numeric flags.
- control results with non-numeric parameter results.

IMPORTANT If you analyzed a control in the wrong file, that run must be excluded from the statistics. If the run is not excluded, the summary data for that control file will be inaccurate.

Reminder:

To deselect a control run:

a. ☑ until ☐ appears.

b. Repeat step a until you have deselected all the runs you want excluded from the statistics.

---

3 Print a copy of the control file data for your records.

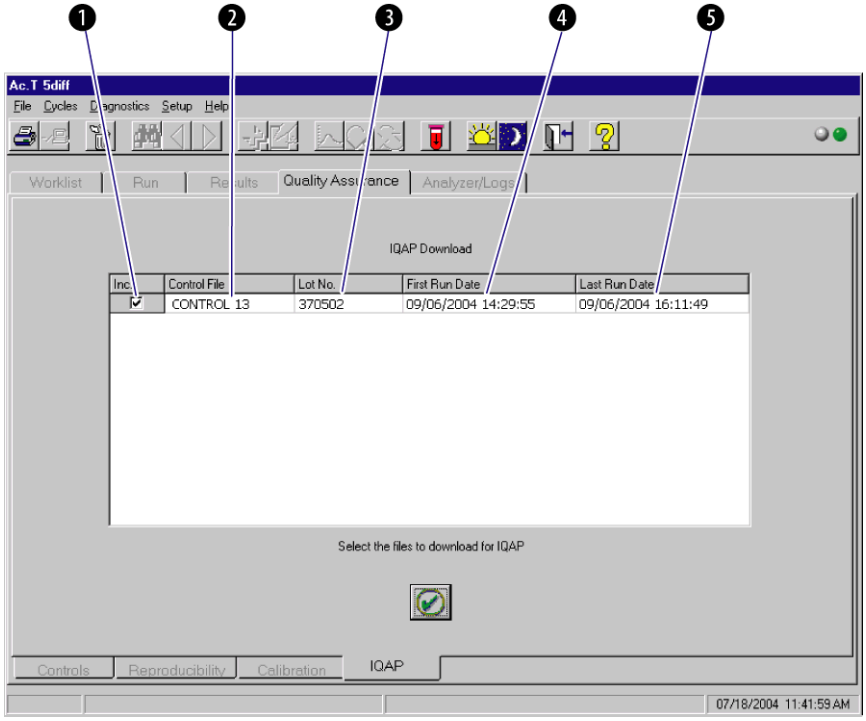
Downloading Results to Diskette for IQAP Submission.

After ***Preparing for IQAP Download*** in this chapter, do this procedure to download the results.

Supplies Needed:

- ❑ Formatted, blank diskette (you provide) or control diskette
- ❑ IQAP labels (provided by Beckman Coulter in your IQAP packet)
- ❑ Board stock return mailers (also provided by Beckman Coulter IQAP)

The IQAP Download Screen



❶ Allows you to include/exclude the file.

❷ Control file name.

❸ Control material lot number.

❹ Date of the first run in the control file.

❺ Date of the last run in the control file.

Note: The only files that are displayed for inclusion in the IQAP download are those that have

- a lot number in the same format as A^{C}•T 5diff Control Plus control material,
- a first run date within the last 3 months, and
- at least one selected result.

Download Procedure

1 the **Quality Assurance** tab.

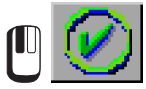
2 the **IQAP** tab.

3 To select a control file to be downloaded:

a. ☐ until ☑ appears.

b. Repeat step a until only the files you want to include in the download are selected.

4 Insert a blank, formatted diskette or a control diskette into the drive A: of the Workstation's PC.

5  .

6 The following message appears:

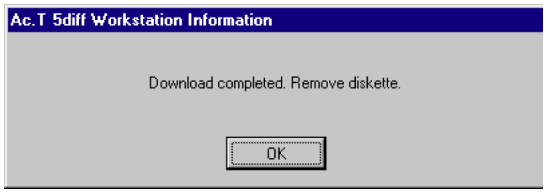
OK to begin the download.

- If the IQAP ID is valid, the system downloads the selected control data to the diskette. The progress indicator in the status bar indicates the progress.
- If the IQAP ID is not valid, the following message appears:
  Invalid IQAP number. IQAP number must be entered before download can occur.

  1) OK.
  2) Verify that the correct IQAP ID was entered into the system.
     See ***Setting Up the IQAP ID***.
  3) Repeat steps 1 through 6.

7 Allow the IQAP download to be completed. Wait for a popup window that displays the message *Download completed. Remove diskette*.

8 OK then remove the diskette.



9 Apply a label (provided by Beckman Coulter's IQAP department) to the diskette. The label identifies the owner of the submission in case the disk becomes corrupted.

10 Insert the diskette into a return mailer and mail it to Beckman Coulter's IQAP department.

7.3 DELETING CONTROL FILES

IMPORTANT Risk of failure to print and/or transmit all requested results. Do not delete result(s) until printing and/or transmitting are complete. Allow all results to complete printing and/or transmitting before using the delete function.

Do this procedure to delete one or more control files.

---

1 Ensure that you have control summary data to fulfill your regulatory requirements prior to deleting control files.

Once a control file is deleted, the control information is gone and cannot be recovered.

---

2 the **Quality Assurance** tab.

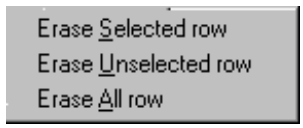
---

3 Select or deselect the rows you want to delete. If you want to erase all rows, you do not have to select them; there is an **Erase all row** option you can choose.

---

4 .

ATTENTION: Control data cannot be recovered once it has been deleted. Therefore, be certain that you want to delete (erase) the control data before you proceed.



5 the desired erase (delete) option. The selected control data will be erased.

8.1 OVERVIEW

This chapter provides information on running patient samples with and without using the Worklist.

- If you want to run sample using the Worklist, do ***Heading 8.4, RUNNING PATIENT SAMPLES USING THE WORKLIST***.
- If you want to run samples without using the Worklist, do ***Heading 8.5, RUNNING PATIENT SAMPLES WITHOUT USING THE WORKLIST***.

8.2 PREPARE THE SYSTEM FOR PROCESSING

IMPORTANT Risk of inaccurate results if the Analyzer is not properly prepared. Follow the prompts, if any, on the screen to perform either a Startup or Mini Prime to prepare the Analyzer. It is not necessary to do both.

If the system has remained idle for a certain period of time, the system will prompt you to do a Startup or a Mini Prime.

8.3 SPECIMEN COLLECTION AND MIXING

Collect whole blood in a salt of EDTA according to tube manufacturer's instructions and procedures in:

- NCCLS publication H4-A3 (for capillary).[4]
- NCCLS publication H3-A3 (for venipuncture).[5]

Beckman Coulter recommends the use of tripotassium EDTA. Dipotassium EDTA is a suitable alternative.

IMPORTANT Risk of erroneous results if the specimen tube is not filled to the quantity required. When collecting samples (venous and capillary) always follow the manufacturer's recommended procedures and fill volumes.

IMPORTANT Risk of erroneous results if sample is not properly mixed before analysis. Mix the blood specimen gently and thoroughly before analysis according to the tube manufacturer's recommendations and your laboratory protocol.

8.4 RUNNING PATIENT SAMPLES USING THE WORKLIST

This procedure provides details on how to run samples using the Worklist.

- For running Worklist samples with autonumbering on, see ***Running Worklist Samples: Autonumbering On***.
- For running Worklist samples with autonumbering off, see ***Running Worklist Samples: Autonumbering Off***.

By analyzing samples using the Worklist, you will have the ability to enter demographics, select flagging sets, enter the Sample ID (required), select the panel, and enter the Patient ID.

Running Worklist Samples: Autonumbering On

If your instrument is configured to the Autonumbering ID mode, the instrument automatically assigns a sample ID (from 1 to 999999) and increments the number before each analysis.

---

1 Prepare the Workstation for sample processing:

a. the **Results** tab.

b. Verify that the active archive is open (white background on Worklist and Results list).

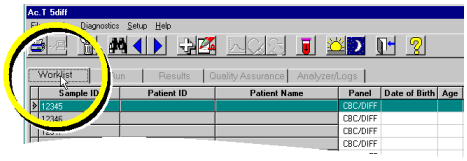
If an old archive is open (green background), **File** ▸▸ **Close Archive**.

c. If, according to your laboratory protocol, it is time to create a new archive, **File** ▸▸ **New Archive**.

Note: You cannot create a new archive until any previously opened archive, if any, is closed.

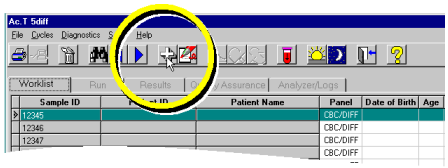
2 Click the **Worklist** tab.

Note: If the Worklist is downloaded from a host computer, the Sample ID and patient demographics are automatically downloaded and cannot be edited.



3 Click to open the Add/Edit Worklist window

For information on changing the starting number, see ***Changing the Starting Number for Autonumbered Sample IDs***.



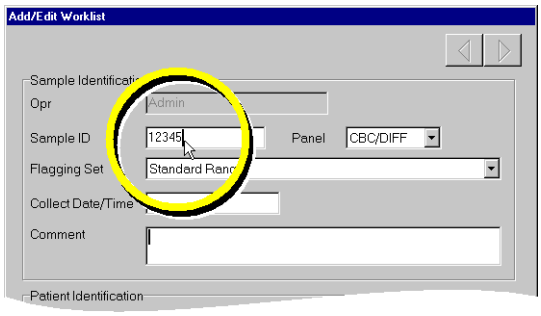
4 Verify that the Sample ID is correct:

Since autonumbering is on, the Sample ID is automatically entered.

To override the number with another Sample ID:

1) Highlight the number in the Sample ID field.
2) Type the desired Sample ID number.
3) Press Tab when the Sample ID is complete.
4) Verify that the Sample ID is correct.

Note: Autonumbering automatically begins again with the autonumber that was overwritten.

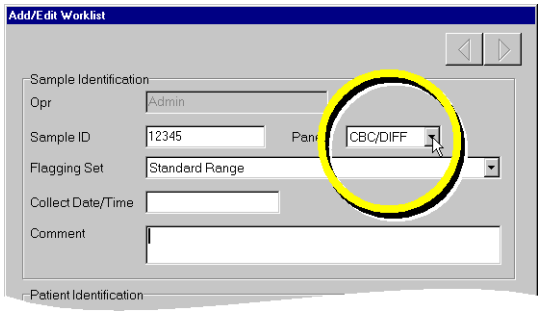


5 Select the panel – **CBC** or **CBC/DIFF**:

a. .

b. Select **CBC** or **CBC/DIFF**.

c. Press Tab to move the cursor to the Flagging Set field.



6 Select another flagging set if appropriate:

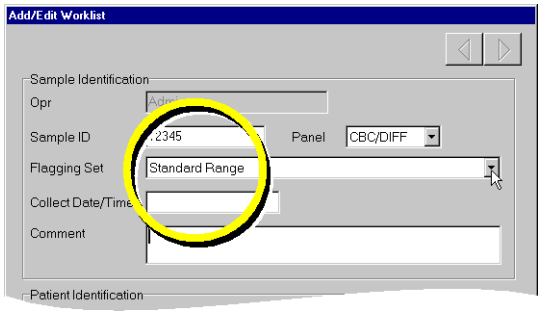
a. .

b. the desired flagging set.

c. Press Tab to move the cursor to the Collection Date and Time field.

If you manually select a flagging set, that flagging set will be applied.

For information on the flagging set hierarchy, see Figure 5.15.

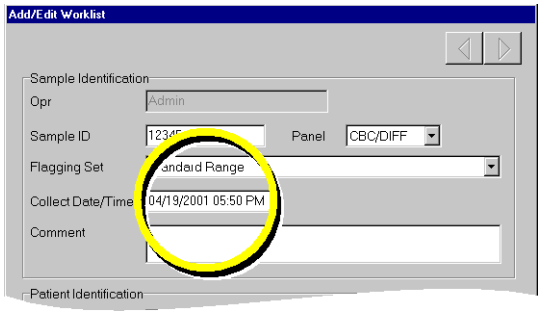


7 Enter the date and time that the specimen was collected:

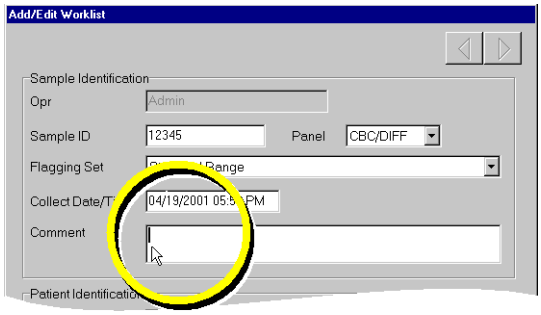
a. Enter the complete date.

b. Enter the time.

c. Press Tab to move the cursor to the Comments field.

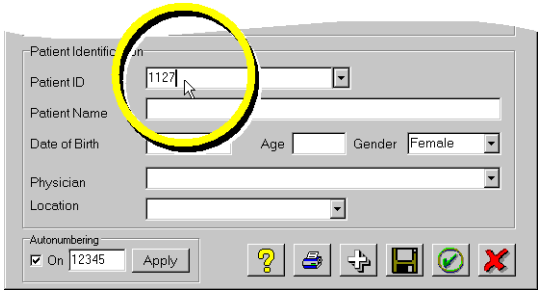


8 Type your comments (optional) and press Tab to move to the Patient ID field.



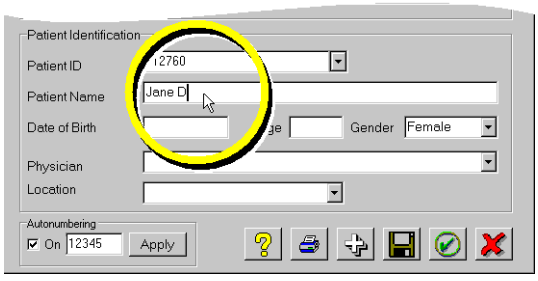
9 Enter the Patient ID (optional) (up to 25 alphanumeric characters and no spaces):

- manually enter the Patient ID, or
- scan the Patient ID from the barcode, if applicable, or
- and select the Patient ID from the existing list of Patient IDs, if applicable.



10 Press Tab to move to the Patient Name field.

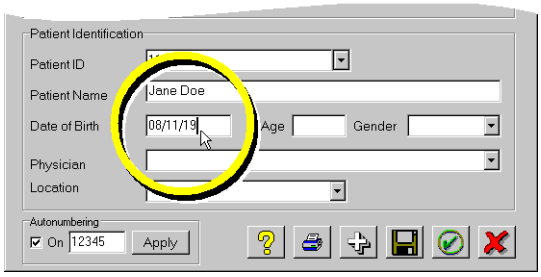
11 Enter the patient's name (up to 30 alphanumeric characters and spaces) and press Tab to move to the date of birth field.



12 Enter the patient's date of birth and press Tab.

The system automatically calculates the patient's age and populates the age field based on the date of birth you entered.

If you do not enter the year, an *invalid date* message appears.



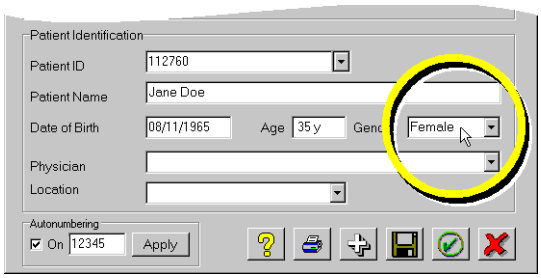
13 Press Tab Tab to move to the patient's gender field.

14 Select the patient's gender:

a. .

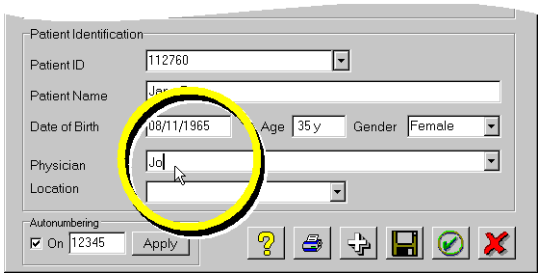
b. Select the gender.

c. Press Tab to move the cursor to the physician's name field.



15 Enter the physician's name (up to 30 alphanumeric characters and spaces):

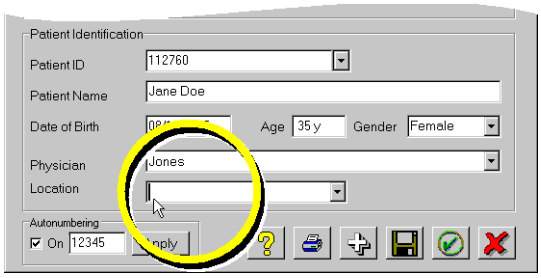
- manually enter the physician's name, or
- and select the physician from the list, if applicable.



16 Press Tab to move the cursor to the Location field.

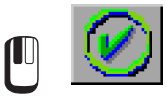
17 Enter the patient's location (up to 15 alphanumeric characters and spaces):

- manually enter the location, or
- and select the location from the existing list of locations, if applicable.



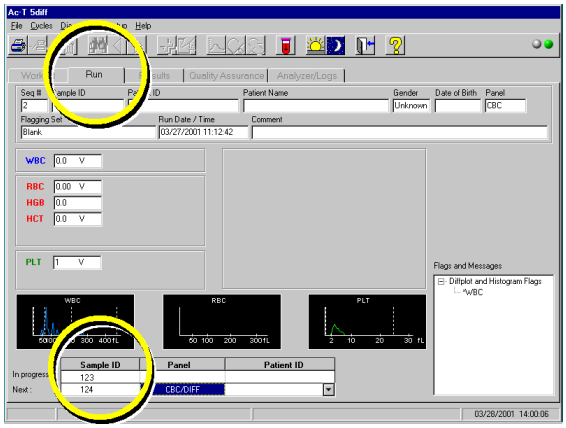
18 to save the information and clear the box for additional entries.

19 When the last entry is added,

 to save and exit.

20 the **Run** tab.

The Sample ID for the next sample to be processed is identified in the Sample ID Next field.



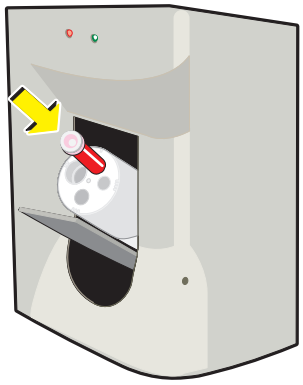
21 Mix the specimen gently and thoroughly according to your laboratory's protocol.

22 If the specimen tube does not have a **pierceable** stopper, remove the stopper.

23 Verify that the Sample ID in the Sample ID Next field matches the sample to be processed.

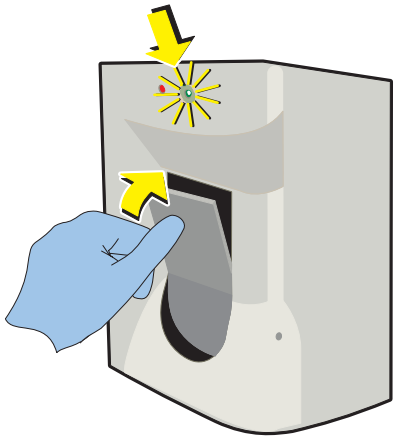
IMPORTANT Risk of sample mis-identification if you do not verify the Sample ID displayed at the Workstation with the Sample ID on the tube prior to analysis.

24 Insert the tube into the correct position of the correct tube holder.



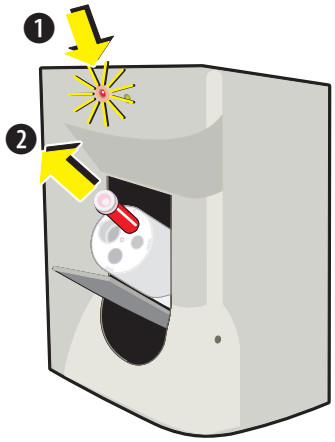
25 Close the tube holder door to begin analysis.

IMPORTANT Do not log out of the Workstation while the Analyzer is running a cycle. Logging out during an Analyzer cycle will cause problems with the Analyzer/Workstation communication.



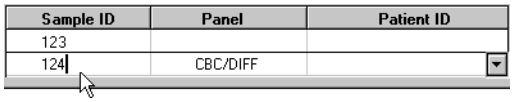
26 Remove the tube when the tube holder door automatically opens (after aspiration).

The red LED is still illuminated, which means the Analyzer is busy processing the sample.



27 Wait for the green LED to illuminate, which indicates the system is ready for the next sample.

Information for the next sample to be processed is displayed in the Sample ID Next field on the Run screen.



28 Verify that the current sample results appear in the Run window.

29 Verify the Sample ID and results before reporting the results.

30 to print a copy of the results.

Note: A copy prints automatically if the Auto-Print function is enabled.

31 Verify that the Sample ID for the next sample is correct.

32 Repeat steps 21 through 31 until all samples are analyzed.

Running Worklist Samples: Autonumbering Off

If autonumbering is disabled on your system, you must manually enter the Sample ID (up to 16 alphanumeric characters) by typing it at the keyboard or by scanning it using the barcode reader (optional).

Barcode configuration is performed at installation.

ATTENTION: Beckman Coulter recommends that you verify each barcode reading to ensure correct sample identification.

---

1 Prepare the Workstation for sample processing:

a. the **Results** tab.

b. Verify that the active archive is open (white background on Worklist and Results list).

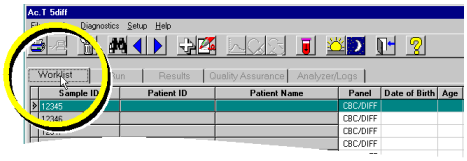
If an old archive is open (green background), **File** ▸▸ **Close Archive**.

c. If, according to your laboratory protocol, it is time to create a new archive, **File** ▸▸ **New Archive**.

Note: You cannot create a new archive until any previously opened archive, if any, is closed.

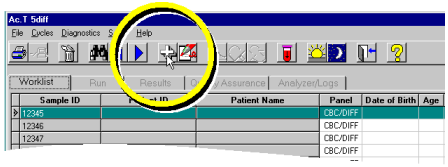
---

2 the **Worklist** tab.



Note: If the Worklist is downloaded from a host computer, the Sample ID and patient demographics are automatically downloaded and cannot be edited.

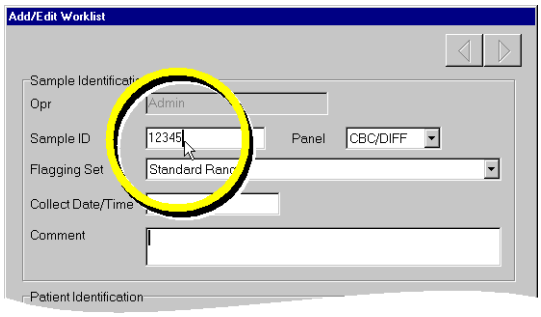
3 to open the Add/Edit Worklist window



4 Enter the Sample ID by typing it or scanning it from the barcode label.

- If scanning the Sample ID go to step 5.
- If typing the Sample ID:

  1) in the Sample ID field.
  2) Type the Sample ID.
  3) Press Enter.
  4) Verify that the Sample ID in the Sample ID field is correct.
  5) Press Tab to move the cursor to the Panel field.
  6) Go to step 6.



IMPORTANT Risk of sample mis-identification if the entire barcode is not captured with the barcode reader, especially with Interleaved 2-of-5 barcode format. Position the barcode reader over the label to capture the entire barcoded sample ID. Otherwise, part of the sample ID may not be scanned, resulting in mis-identification. Pass the barcode reader over the barcode label on the sample tube.

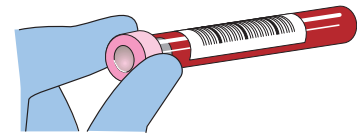
5 Scan the Sample ID from the barcode label on the sample tube.

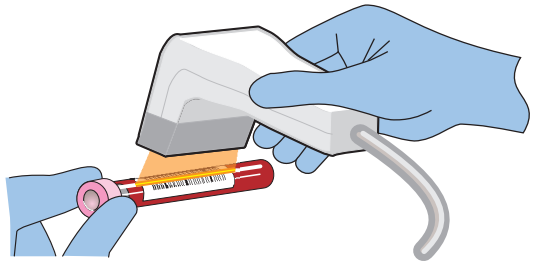
a. Position the barcode reader over the barcode label.

b. Squeeze the trigger button.

If the barcode is successfully read, the barcode reader beeps, the LED on top of the reader illuminates, and the cursor advances to the next field.

c. Verify the barcode reading to ensure that the Sample ID in the Sample ID Next field is correct.



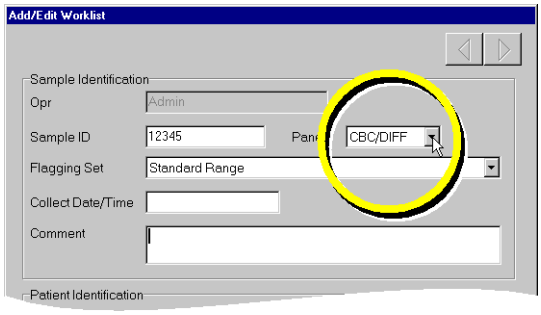


6 Select the panel – **CBC** or **CBC/DIFF**:

a. .

b. Select **CBC** or **CBC/DIFF**.

c. Press Tab to move the cursor to the Flagging Set field.



7 Select another flagging set if appropriate.

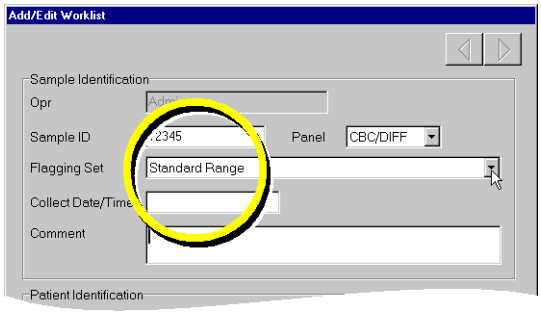
a. .

b. Select the desired flagging set.

c. Press Tab to move the cursor to the Collection Date and Time field.

If you manually select a flagging set, that flagging set will be applied.

For information on the flagging set hierarchy, see Figure 5.15.

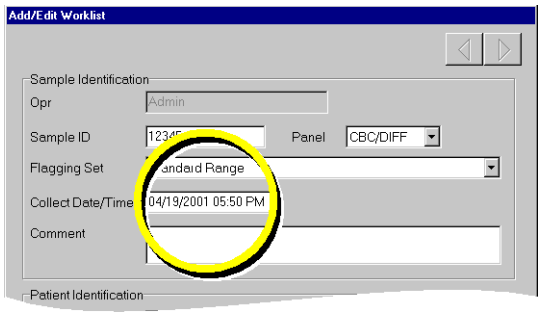


8 Enter the date and time that the specimen was collected:

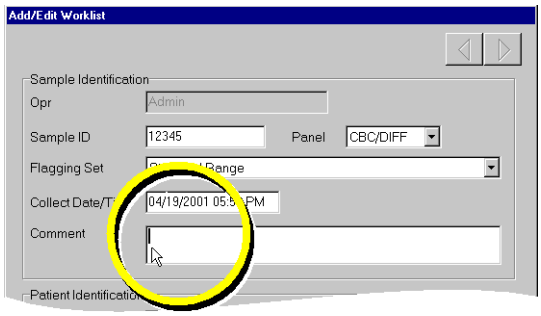
a. Enter the complete date.

b. Enter the time.

c. Press Tab to move the cursor to the Comments field.

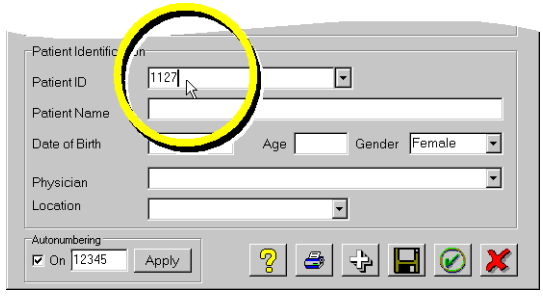


9 Type your comments (optional) and press Tab to move to the Patient ID field.



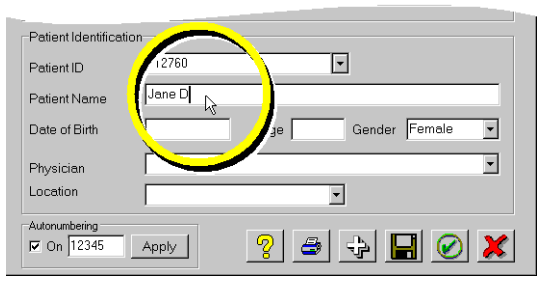
10 Enter the Patient ID (up to 25 alphanumeric characters and no spaces):

- Manually enter the ID, or
- Scan the ID from the barcode, if applicable, or
- and select the ID from the existing list of Patient IDs, if applicable.



11 Press Tab to move to the Patient Name field.

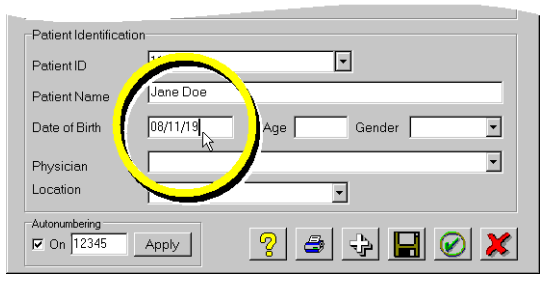
12 Enter the patient's name (up to 30 alphanumeric characters and spaces) and press Tab to move to the date of birth field.



13 Enter the patient's date of birth and press Tab.

The system automatically calculates the patient's age and populates the age field based on the date of birth you entered.

If you do not enter the year, an *invalid date* message appears.



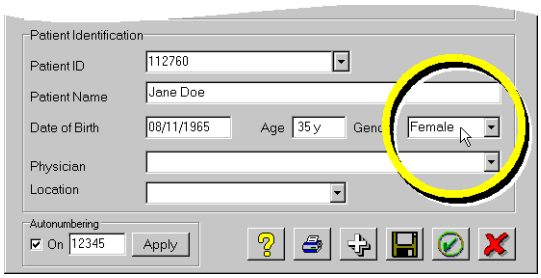
14 Press Tab Tab to move to the patient's gender field.

15 Select the patient's gender:

a. .

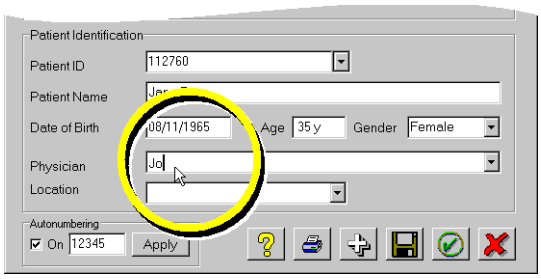
b. Select the gender.

c. Press Tab to move the cursor to the physician's name field.



16 Enter the physician's name (up to 30 alphanumeric characters and spaces):

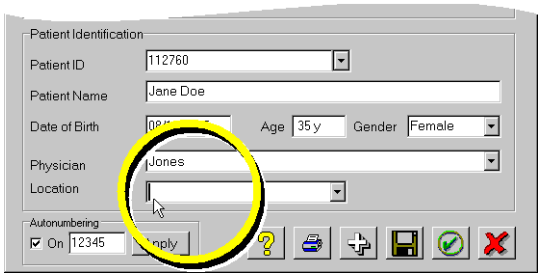
- manually enter the physician's name, or
- and select the physician from the list, if applicable.



17 Press Tab to move the cursor to the Location field.

18 Enter the patient's location (up to 15 alphanumeric characters and spaces):

- manually enter the location, or
- and select the location from the existing list of locations, if applicable.



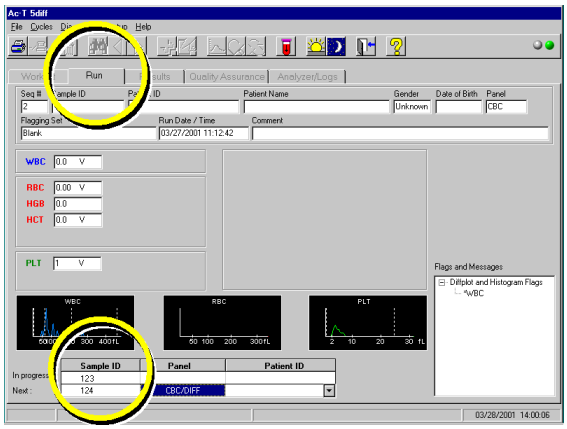
19 to save the information and clear the box for additional entries.

20 When the last entry is added,

to save and exit the window.

21 the **Run** tab.

The Sample ID for the next sample to be processed is identified in the Next Sample ID field.



IMPORTANT Risk of erroneous results if sample is not properly mixed before analysis. Mix the blood specimen gently and thoroughly before analysis according to the tube manufacturer's recommendations and your laboratory protocol.

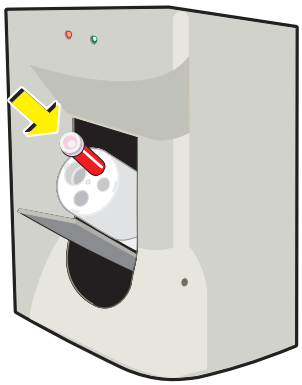
22 Mix the specimen gently and thoroughly.

23 If the specimen tube does not have a **pierceable** stopper, remove the stopper.

24 Verify that the Sample ID in the Sample ID Next field matches the sample to be processed.

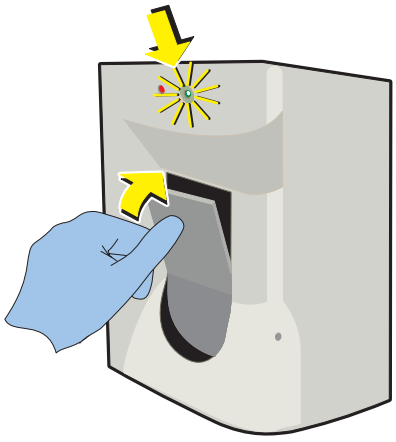
IMPORTANT Risk of sample mis-identification if you do not verify the Sample ID displayed at the Workstation with the Sample ID on the tube prior to analysis.

25 Insert the tube into the correct position of the correct tube holder.



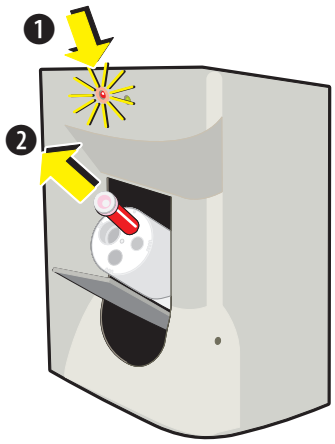
26 Close the tube holder door to begin analysis.

IMPORTANT Do not log out of the Workstation while the Analyzer is running a cycle. Logging out during an Analyzer cycle will cause problems with the Analyzer/Workstation communication.



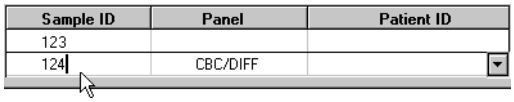
27 Remove the tube when the tube holder door automatically opens (after aspiration).

The red LED is still illuminated, which means the Analyzer is busy processing the sample.



28 Wait for the green LED to illuminate, which indicates the system is ready for the next sample.

Information for the next sample to be processed is displayed in the Sample ID Next field.



29 Verify that the current sample results appear in the Run window.

30 Verify the Sample ID and results before reporting the results.

31 to print a copy of the results.

Note: A copy prints automatically if the Auto-Print function is enabled.

32 Verify that the Sample ID for the next sample is correct.

33 Repeat steps 21 through 31 until all samples are analyzed.

8.5 RUNNING PATIENT SAMPLES WITHOUT USING THE WORKLIST

This procedure provides details on how to run samples **without** using the Worklist.

- For running Worklist samples with autonumbering on, see ***Running Samples: Autonumbering On***.
- For running Worklist samples with autonumbering off, see ***Running Samples: Autonumbering Off***.

You will be required to enter a Sample ID. Samples will be flagged using the selected default flagging set. Panel selection and Patient ID are optional.

Running Samples: Autonumbering On

If your instrument is configured to the Autonumbering ID mode, the instrument automatically assigns a sample ID (from 1 to 999999) and increments the number before each analysis.

---

1 Prepare the Workstation for sample processing:

a. the **Results** tab.

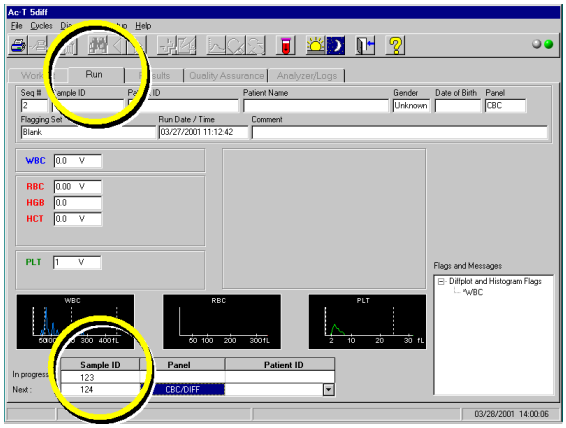
b. Verify that the active archive is open (white background on Worklist and Results list).

If an old archive is open (green background), **File** ▸▸ **Close Archive**.

c. If, according to your laboratory protocol, it is time to create a new archive, **File** ▸▸ **New Archive**.

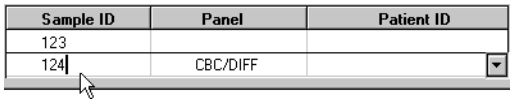
Note: You cannot create a new archive until any previously opened archive, if any, is closed.

2 the **Run** tab.



3 Verify that the Sample ID is correct:

Since autonumbering is on, the Sample ID is automatically entered.



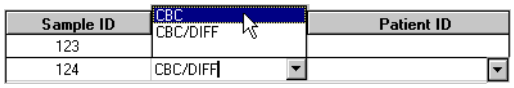
To override the autonumber with another Sample ID:

1) Highlight the autonumber in the Sample ID Next field.
2) Type the desired Sample ID number.
3) Press Tab when the Sample ID is complete.
4) Verify that the Sample ID number is correct.

Note: Autonumbering automatically begins again with the autonumber that was overwritten.

4 Press Tab to move the cursor to the Panel field.

5 Select the panel – **CBC** or **CBC/DIFF**:

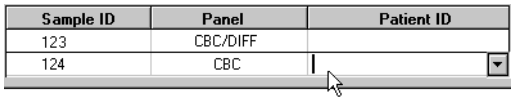


a. .

b. Select **CBC** or **CBC/DIFF**.

c. Press Tab to move the cursor to the Patient ID field.

6 Enter the Patient ID (optional) (up to 25 alphanumeric characters and no spaces):



- Manually enter the Patient ID, or
- Scan the Patient ID from the barcode, if applicable, or
- and select the ID from the existing list of Patient IDs, if applicable.

IMPORTANT Risk of erroneous results if sample is not properly mixed before analysis. Mix the blood specimen gently and thoroughly before analysis according to the tube manufacturer's recommendations and your laboratory protocol.

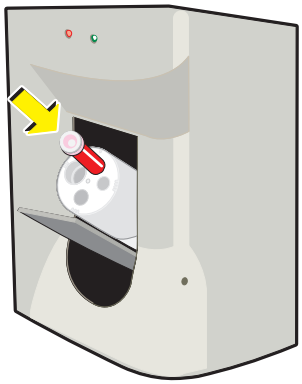
7 Mix the specimen gently and thoroughly.

8 If the specimen tube does not have a **pierceable** stopper, remove the stopper.

9 Verify that the Sample ID in the Sample ID Next field matches the sample to be processed.

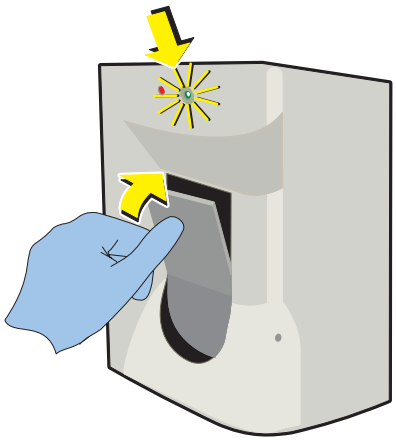
IMPORTANT Risk of sample mis-identification if you do not verify the Sample ID displayed at the Workstation with the Sample ID on the tube prior to analysis.

10 Insert the tube into the correct position of the correct tube holder.



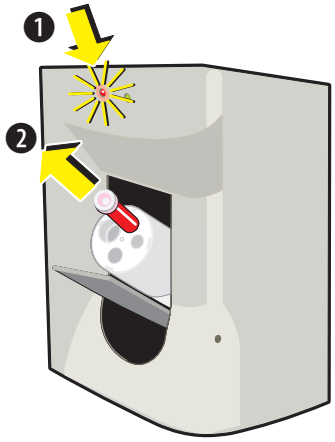
11 Close the tube holder door to begin analysis.

IMPORTANT Do not log out of the Workstation while the Analyzer is running a cycle. Logging out during an Analyzer cycle will cause problems with the Analyzer/Workstation communication.



12 Remove the tube when the tube holder door automatically opens (after aspiration).

The red LED is still illuminated, which means the Analyzer is busy processing the sample.



13 Wait for the green LED to illuminate, which indicates the system is ready for the next sample.

Information for the next sample to be processed is displayed in the Sample ID Next field.

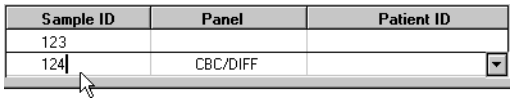
14 Verify that the current sample results appear in the Run window.

15 Verify the Sample ID and results before reporting the results.

16 to print a copy of the results.

Note: A copy prints automatically if the Auto-Print function is enabled.

17 Verify that the Sample ID for the next sample is correct:



18 Repeat steps 3 through 17 until all samples are analyzed.

Running Samples: Autonumbering Off

If autonumbering is disabled on your system, you must manually enter the Sample ID (up to 16 alphanumeric characters) by typing it at the keyboard or by scanning it using the barcode reader (optional).

Barcode configuration is performed at installation.

ATTENTION: Beckman Coulter recommends that you verify each barcode reading to ensure correct sample identification.

---

1 Prepare the Workstation for sample processing:

a. Click the **Results** tab.

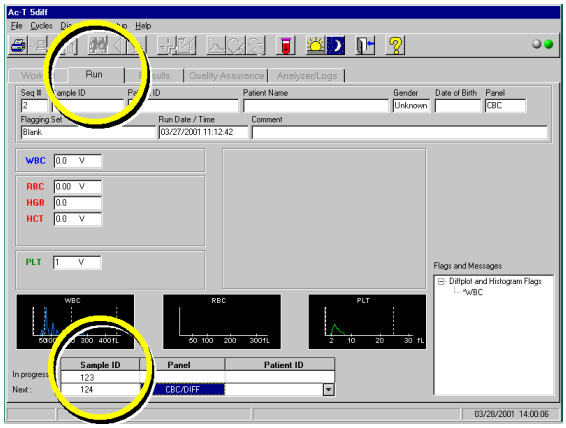
b. Verify that the active archive is open (white background on Worklist and Results list).

If an old archive is open (green background), **File** ▸▸ **Close Archive**.

c. If, according to your laboratory protocol, it is time to create a new archive, **File** ▸▸ **New Archive**.

Note: You cannot create a new archive until any previously opened archive, if any, is closed.

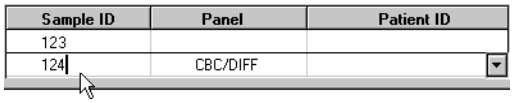
2 the **Run** tab.



3 Enter the Sample ID by typing it or scanning it from the barcode label.

- If scanning the Sample ID go to step 4.
- If typing the Sample ID:

  1) in the Sample ID Next field.
  2) Type the Sample ID.
  3) Press Enter.
  4) Verify that the Sample ID in the Sample ID Next field is correct.
  5) Press Tab to move the cursor to the Panel field.
  6) Go to step 5.



IMPORTANT Risk of sample mis-identification if the entire barcode is not captured with the barcode reader, especially with Interleaved 2-of-5 barcode format. Position the barcode reader over the label to capture the entire barcoded sample ID. Otherwise, part of the sample ID may not be scanned, resulting in mis-identification. Pass the barcode reader over the barcode label on the sample tube.

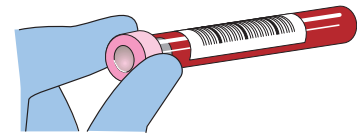
4 Scan the Sample ID from the barcode label on the sample tube.

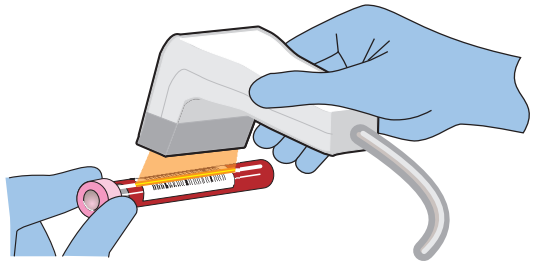
a. Position the barcode reader over the barcode label.

b. Squeeze the trigger button.

If the barcode is successfully read, the barcode reader beeps, the LED on top of the reader illuminates, and the cursor advances to the next field.

c. Verify the barcode reading to ensure that the Sample ID in tn the Sample ID Next field is correct.



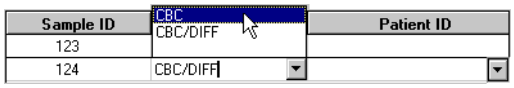


5 Select the panel – **CBC** or **CBC/DIFF**:

a. .

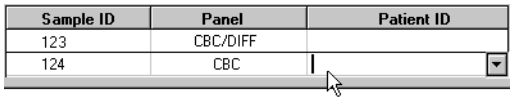
b. Select **CBC** or **CBC/DIFF**.

c. Press Tab to move the cursor to the Patient ID field.



6 Enter the Patient ID (optional) (up to 25 alphanumeric characters and no spaces):

- manually enter the ID, or
- scan the ID from the barcode, if applicable, or
- and select the ID from the existing list of Patient IDs, if applicable.



IMPORTANT Risk of erroneous results if sample is not properly mixed before analysis. Mix the blood specimen gently and thoroughly before analysis according to the tube manufacturer's recommendations and your laboratory protocol.

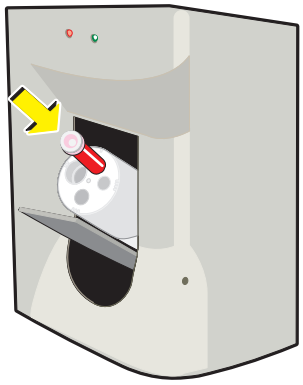
7 Mix the specimen gently and thoroughly.

8 If the specimen tube does not have a **pierceable** stopper, remove the stopper.

9 Verify that the Sample ID in the Sample ID Next field matches the sample to be processed.

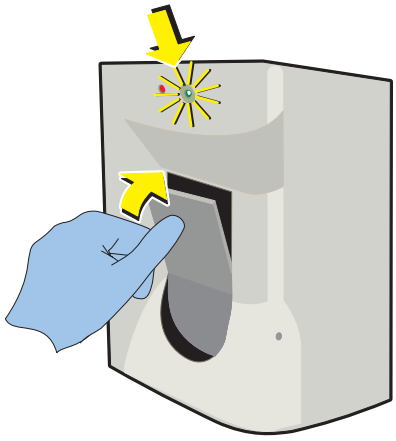
IMPORTANT Risk of sample mis-identification if you do not verify the Sample ID displayed at the Workstation with the Sample ID on the tube prior to analysis.

10 Insert the tube into the correct position of the correct tube holder.



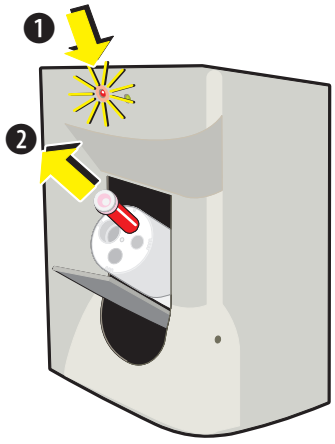
11 Close the tube holder door to begin analysis.

IMPORTANT Do not log out of the Workstation while the Analyzer is running a cycle. Logging out during an Analyzer cycle will cause problems with the Analyzer/Workstation communication.



12 Remove the tube when the tube holder door automatically opens (after aspiration).

The red LED is still illuminated, which means the Analyzer is busy processing the sample.



13 Wait for the green LED to illuminate, which indicates the system is ready for the next sample.

Information for the next sample to be processed is displayed on the screen.

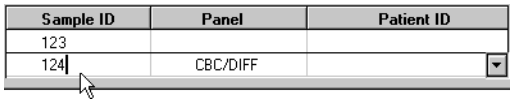
14 Verify that the current sample results appear in the Run window.

15 Verify the Sample ID and results before reporting the results.

16 to print a copy of the results.

Note: A copy prints automatically if the Auto-Print function is enabled.

17 Verify that the Sample ID for the next sample is correct:



18 Repeat steps 3 through 17 until all samples are analyzed.

8.6 RUNNING STAT SAMPLES FROM WORKLIST ENTRIES

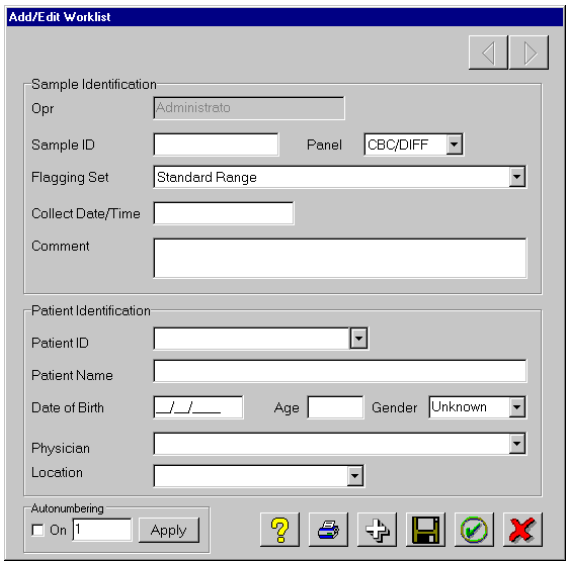
Do this procedure to run a stat sample for:

- a sample ID that does not exist on the Worklist, or
- a sample ID that already exists on the Worklist.

You cannot select multiple entries from the Worklist to be run as stat samples. The samples are processed based on entry into the Worklist. Therefore, if you have more than one stat sample to process from the Worklist, repeat the procedure below as required.

---

1 If the sample is **not** on the Worklist, enter the demographic information:



a. the **Worklist** tab.

b. .

c. Enter the Sample ID (required).

d. Enter the demographic information (optional):

1) Enter the Patient ID or if it has already been entered, select the ID from the pull-down list. Any previously entered information will be displayed.

2) Enter the information.

3) to save.

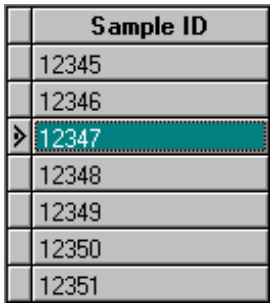
e. Go to step 3.

2 If the sample is on the Worklist, locate the sample:

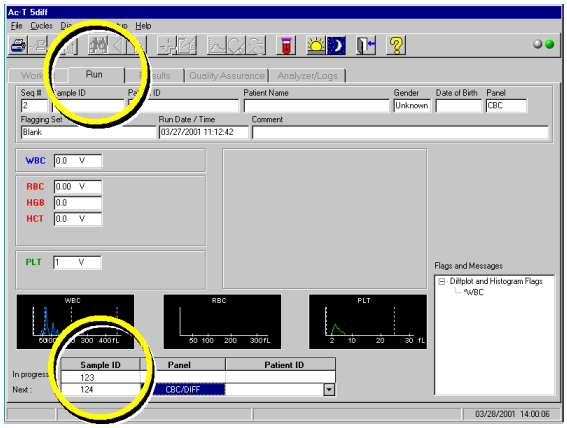
a. the **Worklist** tab.

b. Locate the sample that you want processed as a “stat” sample.

c. the far left column to mark the sample as “next to be processed”.



3 Run the stat sample:



a. the **Run** tab.

b. Verify that the starting Sample ID appears for the sample you entered and selected in step a.

- If the starting Sample ID is correct, go to step c.
- If the starting Sample ID is not correct, repeat step a.

IMPORTANT Risk of erroneous results if sample is not properly mixed before analysis. Mix the blood specimen gently and thoroughly before analysis according to the tube manufacturer's recommendations and your laboratory protocol.

c. Mix the specimen gently and thoroughly.

d. Verify that the Sample ID is correct.

IMPORTANT Risk of sample mis-identification if you do not verify the Sample ID displayed at the Workstation with the Sample ID on the tube prior to analysis.

e. Place the sample tube in the correct tube holder position.

f. Verify that the tube holder is positioned such that the sample tube is in the 12:00 o'clock pierce position.

g. Close the tube holder door.

IMPORTANT Do not log out of the Workstation while the Analyzer is running a cycle. Logging out during an Analyzer cycle will cause problems with the Analyzer/Workstation communication.

The sample is highlighted in red in the Worklist during analysis. When analysis is complete, the sample is removed from the Worklist and placed with the results in the Results list.

The system displays the Sample ID of the next sample to be processed based on the order of the Worklist before the Stat entry.

4 Review the sample results.

5 Verify the Sample ID and results before reporting the results.

6 to print a copy of the results.

Note: A copy prints automatically if the Auto-Print function is enabled.

8.7 RERUNNING SAMPLES

There may be instances when you will want to repeat a sample. For example, you may want to rerun a sample to confirm a suspect result. Due to the duplicate ID feature, rerunning a sample requires using the system's Rerun feature.

If the ID of the sample to be repeated was manually re-entered into the instrument, a "*Duplicate Sample ID*" message is displayed and the sample cannot be processed. You can indicate you want to rerun any sample from the Results screen or the Detailed Results screen. From the Run screen, you can indicate you want to rerun the last sample.

---

1 Locate the results of the sample you want to rerun.

See ***Heading 9.1, LOCATING SAMPLE RESULTS*** for details.

ATTENTION: If you are in the Results List view, verify that the correct result is selected.

2 .

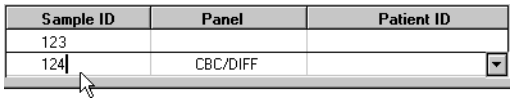
The system automatically places the Sample ID onto the worklist and allows it to be processed as a "rerun".

A red square, indicating that the sample is a re-run, appears at the top right of the screen if you are in the Detailed Results view.

---

3 the **Run** tab.

4 Verify that the correct Sample ID is displayed.



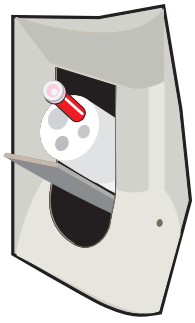
5 Mix the specimen gently and thoroughly according to your laboratory's protocol.

6 If the specimen tube does not have a pierceable stopper, remove the stopper.

7 Verify that the Sample ID in the Sample ID Next field matches the sample to be processed.

IMPORTANT Risk of sample mis-identification if you do not verify the Sample ID displayed at the Workstation with the Sample ID on the tube prior to analysis.

8 Insert the tube into the correct position of the tube holder.

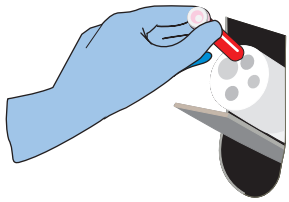


9 Close the tube holder door to begin analysis.

IMPORTANT Do not log out of the Workstation while the Analyzer is running a cycle. Logging out during an Analyzer cycle will cause problems with the Analyzer/Workstation communication.

10 Remove the tube when the tube holder door automatically opens.

Note: The door opens after analysis is completed.



11 Review the sample results.

The results from the first analysis and the re-run appear on the Results List in the order they were processed.

12 Verify the Sample ID and results before reporting the results.

13 to print a copy of the results.

Note: A copy prints automatically if the Auto-Print function is enabled.

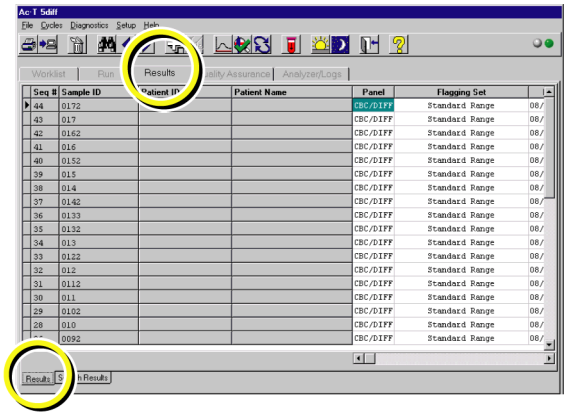
9.1 LOCATING SAMPLE RESULTS

After a sample has been analyzed, you can review the results.

Note: Results that appear on a red background indicate an *HH* or *LL* flag (outside action limits). Results that appear on a yellow background indicate an H or L flag (outside patient limits). See ***Heading 9.3, REVIEWING FLAGGED RESULTS*** for details.

Searching for a Recent Result

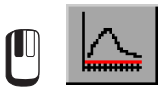
1 the **Results** tab at the top and then the **Results** tab at the bottom. A list of the samples analyzed in the current archive is displayed. Results can be viewed by scrolling.



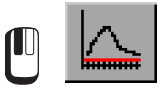
2 To view detailed results:

- Double-click the desired result.

  OR

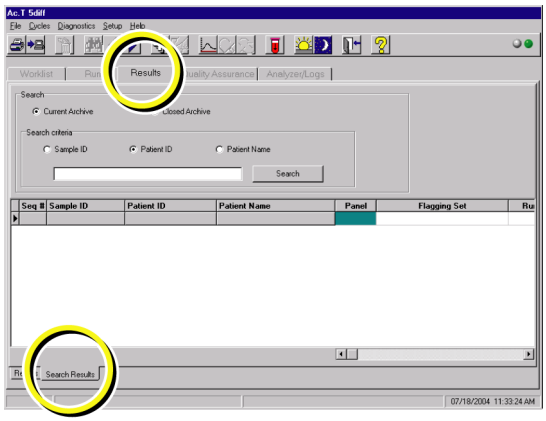
-  to view the details.

  The data is displayed as it was on the Run screen with results and DiffPlots.

3 To return to the list,  .

Advanced Search

1 the **Results** tab at the top then the **Search Results** tab at the bottom.



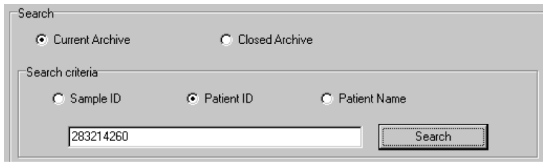
2 Set up the search:

a. **Current Archive** or **Closed Archive**.

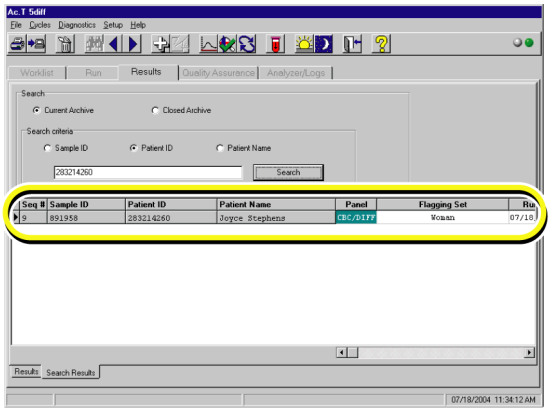
b. choice of search criteria; **Sample ID**, **Patient ID** or **Patient Name**.

c. Type the chosen identifier.

Note: The search entry must match the database entry exactly to return a result. Patient Name is not case sensitive.



3 the **Search** button. If there are any matches, they display.



4 To view detailed results:

- Double-click the desired result.

  OR

- to view the details.

  The data is displayed as it was on the Run screen with results and DiffPlots.

5 To return to the list, .

6 To print from the Search Results list:

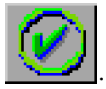
a. Press the Ctrl key and on each sample you want to print.

b. Verify that a black dot

or appears in the far left column of each selected sample and that the row is highlighted.

c. to display the print menu.

d. Select your choice of print option.

e.  .

Sorting Sample Results

You can sort results in ascending or descending order at the Results window. Information can be sorted by:

- Seq. # (sequence number*),
- Sample ID,
- Patient ID, or
- Patient Name.

* The sequence number is instrument generated. It resets to 1 when a new archive is created.

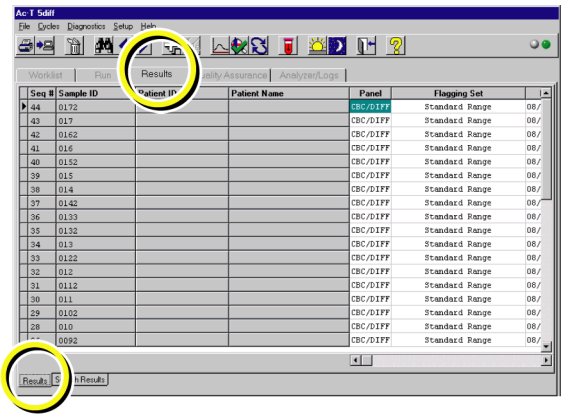
The fields sort alphanumerically by character. For example, 10 will appear before 4 because it is being sorted by the “1”.

Numbers appear in a sorted list before letters. For example, Sample ID 482 will appear before Sample ID N482 (unless sorted in descending order).

Do this procedure to sort results.

---

1 the **Results** tab at the top and the **Results** tab at the bottom, if necessary.



---

2 the title of the column you want sorted. For example, to sort by the Sample ID, the Sample ID column title.

The information is sorted and displayed in ascending (low to high) order.

>> next to the title indicates ascending order and << indicated descending order.

---

3 To sort that same column in descending order, the column title again.

---

4 To return the results list to its original order, **Default Sort.**

9.2 AFTER LOCATING THE SAMPLE RESULTS

After locating a sample result, you can view, print, transmit, validate or delete results.

Viewing Sample Results

1 Select the sample you want to view.

2 To view numeric (tabular) sample results, scroll right.

3 To view detailed results:

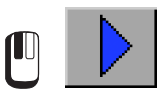
- Double-click the desired result.

  OR

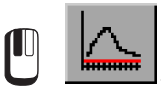
- to view the details.

  The data is displayed as it was on the Run screen with results and DiffPlots.

4 To review previous and next results:

- for the previous result.
-  for the next result.

5 To return to the results list,

 .

Printing Sample Results

You can print a single sample result or batch print a group of sample results.

Printing a Single Sample Result

1 Select the sample result you want to print.

2 to display the print menu.

3 Select the desired print format:

- To print only numeric results,

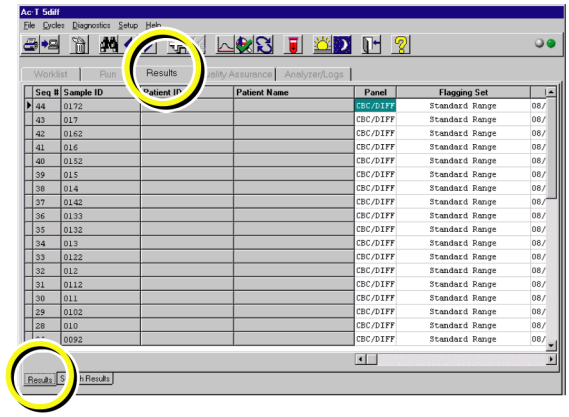
  Print Summary List For Selected Rows.
- To print the Run view of results and DiffPlots, **Print Patient Report For Selected Rows**.

Printing a Batch of Sample Results

IMPORTANT Risk of compromising system functionality if you batch print and/or batch transmit while receiving a Worklist download from a host and/or while analyzing samples with autotransmit on and autoprint on. Always allow sample analysis and/or the host download to complete before batch printing and/or batch transmitting.

IMPORTANT Risk of failure to print and/or transmit all requested results. Do not delete result(s) until printing and/or transmitting are complete. Allow all results to complete printing and/or transmitting before using the delete function.

1 the **Results** tab at the top and then the **Results** tab at the bottom, if necessary.



2 Select each sample result that you want to print:

a. Press the Ctrl key and on each sample you want to print.

b. Verify that a black dot or appears in the far left column of each selected sample and that the row is highlighted.

3 to display the print menu.

4 Select the desired print format:

- To print only numeric results,

  Print Summary List For Selected Rows.

- To print the Run view of results and DiffPlots, **Print Patient Report For Selected Rows**.

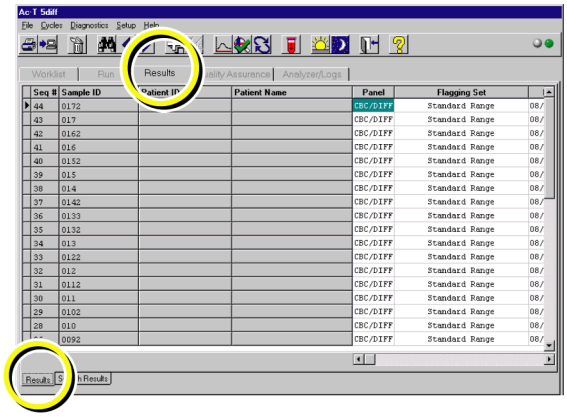
Transmitting Sample Results

You can transmit the last sample result or batch transmit a group of sample results to a host computer (if applicable).

Sample results will automatically be transmitted to a host computer if the Autotransmission option is selected and the settings have been defined.

Transmitting the Last Sample Result

1 the **Results** tab at the top and then the **Results** tab at the bottom, if necessary.



2 .

3 **The last result**.

4 **OK**.

The system transmits the last sample result to the host computer.

Transmitting a Batch of Sample Results

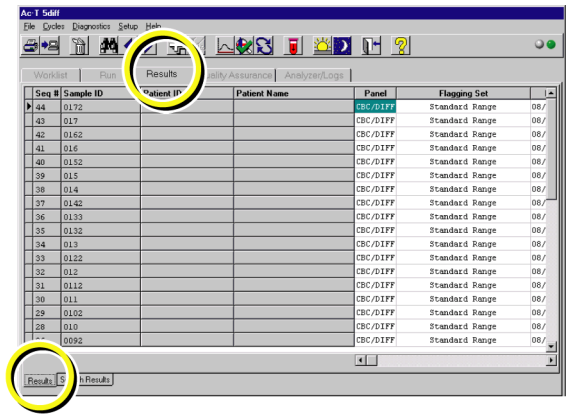
IMPORTANT Risk of compromising system functionality if you batch print and/or batch transmit while receiving a Worklist download from a host and/or while analyzing samples with autotransmit on and autoprint on. Always allow sample analysis and/or the host download to complete before batch printing and/or batch transmitting.

IMPORTANT Risk of failure to print and/or transmit all requested results. Do not delete result(s) until printing and/or transmitting are complete. Allow all results to complete printing and/or transmitting before using the delete function.

In addition to selecting specific results to batch transmit, you can also select to transmit all results.

Once transmission begins, it cannot be stopped.

1 the **Results** tab at the top and then the **Results** tab at the bottom, if necessary.



2 Select each sample result that you want to transmit:

a. Press the Ctrl key and on each sample you want to transmit.

b. Verify that a black dot

or appears in the far left column of each selected sample and that the row is highlighted.

3 .

4 **The selected results**.

5 **OK**.

The system transmits the selected results to the host computer.

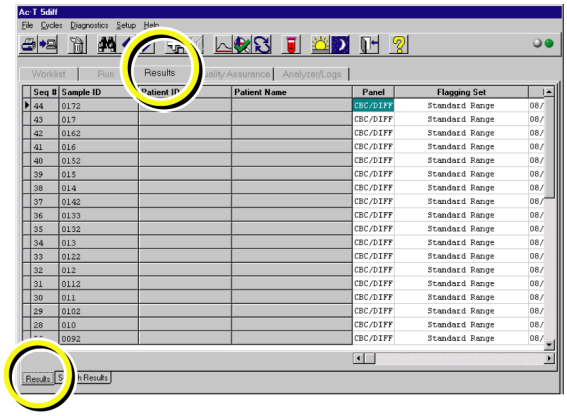
Validating Sample Results

The validation feature provides a visual confirmation that a specific result has been reviewed and validated. Before marking a sample result as validated, remember:

- You cannot rerun a sample that has been marked as validated.
- You cannot validate the first run of a sample once a you request a rerun of that sample.
- You cannot "unvalidate" a validated sample.

Do this procedure if you want to mark the sample result as having been validated.

1 the **Results** tab at the top and then the **Results** tab at the bottom, if necessary.

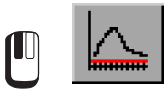

Ac·T 5diff
File Cycles Diagnostics Setup Help
Worklist Run Results Quality Assurance Analyzer/Logs
Seq # Sample ID Patient ID Patient Name Panel Flagging Set
Results

2 Highlight the sample result that you want to mark as validated.

ATTENTION: Remember that you cannot rerun a validated sample, and you cannot validate the first run of a sample once you request a rerun of that sample.

3 .

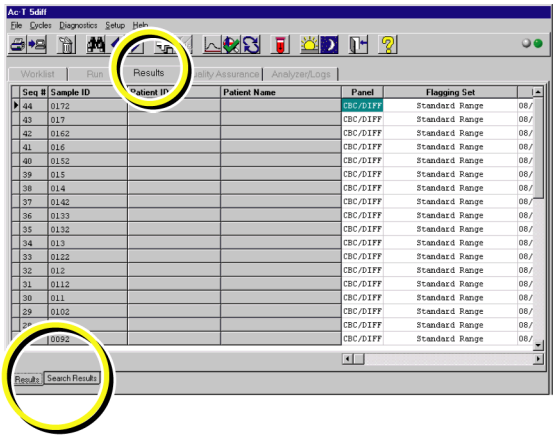
4 Verify that the sample has been validated:

a.  .

b. Verify that the box in the upper right corner is now green.

Deleting Sample Results

IMPORTANT Risk of failure to print and/or transmit all requested results. Do not delete result(s) until printing and/or transmitting are complete. Allow all results to complete printing and/or transmitting before using the delete function.


Ac·T 5diff
File Cycles Diagnostics Setup Help
Worklist Run Results Quality Assurance Analyzer/Logs
Seq # Sample ID Patient ID Patient Name Panel Flagging Set
Results Search Results

1 Click the **Results** tab at the top and then the **Results** or **Search Results** tab at the bottom.

Notes:

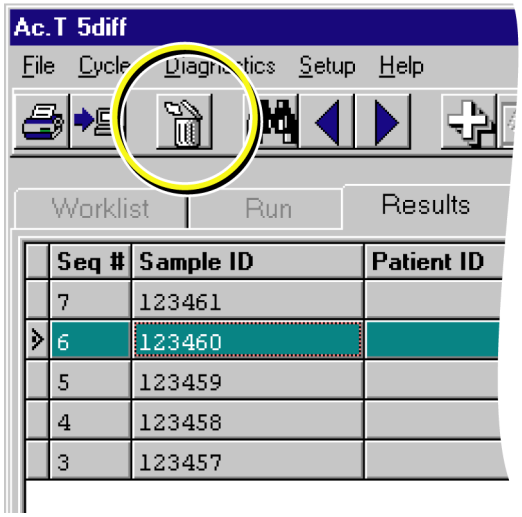
- Use the Result List View (**Results** tab at the bottom) to delete sample results from the current archive.
- Use the **Search Results** tab view to search for and delete sample results from either the current or closed archives.

2 Select each sample result that you want to delete:

a. Press the Ctrl key and click on each sample you want to delete.

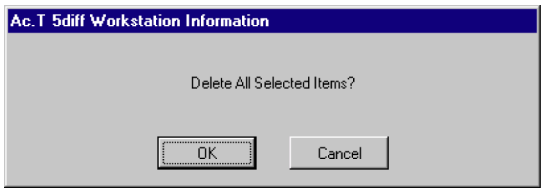
b. Verify that a black dot appears or appears in the far left column of each selected sample and that the row is highlighted.

3 .



4 **OK**.

The system deletes the selected results.



9.3 REVIEWING FLAGGED RESULTS

IMPORTANT Beckman Coulter Inc. does not claim to identify every abnormality in all samples. Beckman Coulter suggests using all available flagging options to optimize the sensitivity of instrument results. All flagging options include Patient Limits (H/L), Action Limits (HH/LL), Parameter Flags, Interpretive Messages and Analytical Alarms. Beckman Coulter recommends avoiding the use of single messages or outputs to summarize specimen results or patient conditions. Additionally, it is recommended that platelet counts less than 20 X 10^3/µL be reviewed.

IMPORTANT Risk of result inaccuracy if a transient or partial blockage is not detected by the instrument. In rare instances, especially for samples where fibrin or other debris is likely to occur (such as pediatric or oncology samples), a transient or partial blockage may not be detected by the instrument. Therefore, verify flagged results for accuracy and review any result that exceeds your laboratory's limits.

General

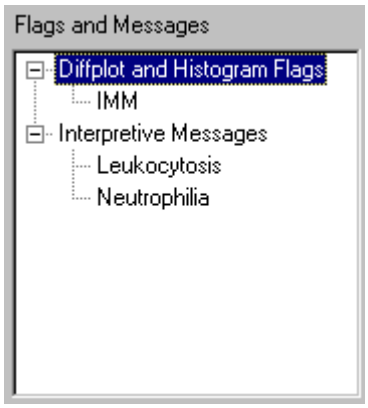
Patient sample results are generated from sample analysis. There may be instances when a patient sample result is flagged or a parameter number is replaced by a flag.

Carefully review all patient sample results, especially results with flags and/or messages. For details, see ***Flags and Analytical Alarms Generated by the Instrument*** and ***Interpretive Messages***.

Flags and messages appear in on the Run screen in a special area (Figure 9.1) and initially appear in a collapsed view. Figure 9.2 shows the expanded view. You may need to scroll to view all the messages.

Figure 9.1 Flags/Messages: Collapsed View:

Figure 9.2 Flags/Messages: Expanded View



- ⊞ to expand the list.
- ⊟ to collapse the list.

Types of Flagging Formats

The system provides two formats for reporting the information that is presented in the Flags and Messages box – **Detailed** and **Suspect**.

- If the Detailed Flags option is selected, samples are flagged using the Detailed format (default).
- If the Detailed Flags option is not selected, samples are flagged using the Suspect format.

Suspect Flag Format

If the Detailed Flags option is not selected (optional setting) at the Reports setup screen, the flags are reported (displayed and printed) in the **Suspect** format as follows:

- DB prints as DB.
- The DIFF flag replaces the SL, SL1, NL, MN, UM, LN, UN, and NE flags.
- IMM prints as IMM.
- ATL prints as ATL.
- The WBC/BA flag replaces the DIFF+, DIFF-, *WBC, MB, and BASO+ flags.
- The HISTO flag replaces the MICRO, MACRO, SCL, MIC, and SCH flags.
- The flags will be printed on the patient report in the area labeled “SUSPECT”.

Detailed Flag Format

If the Detailed option is selected (default) at the system’s Reports setup screen, the flags are reported (displayed and printed) in the detailed format.

Flags, Interpretive Messages, and Analytical Alarms

Flags

• Definition

A flag is a symbol, set of symbols, or letters generated by the instrument to signal that a certain parameter requires additional attention. Flags can appear in a number of ways:

- Linked to a result when it exceeds the normal limits.
- Linked to a problem in the morphology of the blood cell population.
- Linked to instrument operation.

For details, see ***Flags and Analytical Alarms Generated by the Instrument***.

• Types of Flags

This instrument uses two types of flags – replacement and non-replacement flags.

- Replacement flags, also called codes, replace a parameter’s numeric results.
- Non-replacement flags appear next to the parameter results. Up to two of these flags can be displayed for a parameter.
- DiffPlot and Histogram flags appear in the Flags and Messages box in the lower right corner of the Results screen.

Interpretive Messages

• Definition

Interpretive messages are triggered from the action limits established by your laboratory. These messages, which appear in the Flags and Messages box of the Results screen, indicate possible pathological disorders. For details, see ***Interpretive Messages***.

ATTENTION: In rare instances, samples with an unusually high number of flags may not have all interpretive messages printed in the Flags and Messages area of the patient sample report. However, all messages are displayed on the screen, and the flag and/or conditions triggering the interpretive message will appear on the printout and screen.

Analytical Alarms

• Definition

Analytical Alarms, which also appear in the Flags and Messages box of the Run screen, are messages generated by the Analyzer. These messages indicate conditions that may be related to Analyzer operation and indicate if results will be influenced by these conditions.

Flags and Analytical Alarms Generated by the Instrument

Overview

The following sections define these instrument-generated flags:

- Results Exceeding Instrument Capacity,
- Hemoglobin Flags,
- Voteout Flag,
- WBC Count Flag and Analytical Alarms,
- DiffPlot Flags and Analytical Alarms,
- RBC Histogram Flags,
- Plt Histogram Flags and Analytical Alarms, and
- Patient Ranges and Action Ranges.

Results Exceeding Instrument Capacity

If a result exceeds instrument capacity, the result will be indicated as follows:

- If the result is below the lower limits of the instrument, the result will be reported as *0*.

  For example, if the WBC is less than $0.1x10^3/\mu L$, WBC is reported as 0.0.
- If the result is outside the limits at which the parameter can be calculated, the result is replaced by **. . . .**.
- If the result is above the instrument's linear range (Table 3.3), the result is flagged with **+**, or if the result is above the instrument's reportable range (Table 3.6), the result is replaced by **++++**.

  For example, if the WBC is greater than $100x10^3/\mu L$, the WBC result is replaced by **++++**.

  Additionally, related parameters may also be flagged or replaced.

Hemoglobin Flags

• Hemoglobin/Hematocrit Ratio Flag (H & H Flag)

If the [(Hgb g/dL x 3)/Hct%] is <0.8 or >1.2, the RBC, Hgb, MCV, Hct, MCH, MCHC, Plt, MPV, Pct, and PDW will be flagged with *. The presence of this flag indicates that there may have been an error in the analytical process.

• Hgb Blank Error

The instrument establishes a reference blank reading and compares each sample blank to the reference result. If the blank differs from the reference by more than an allowable amount, the Hgb, MCH, and MCHC results are flagged with a review "*R*" flag.

If three consecutive samples produce a Hgb blank error, the Hgb, MCH, and MCHC results are replaced by **. . . .** on the third sample.

• Hgb Read Error

The instrument reads each sample three times. If the difference among the three readings exceeds a predefined limit, the Hgb, MCH, and MCHC results are flagged with a voteout "*V*" flag.

Voteout Flag

The instrument performs two counts on the WBC, RBC, Hct, and Plt. If the results for the two counts differ by more than a predefined limit, the WBC, RBC, Hct, and Plt results are flagged with a voteout "*V*" flag.

- If the WBC result is flagged with a *V*, then the DIFF number results are also flagged with a *V*.
- If the RBC result is flagged with a *V*, then the MCV, MCH, MCHC, and RDW results are replaced by **. . . .**.
- If the Hct result is flagged with a *V*, then the MCV and MCHC results are replaced by **. . . .**.
- If the Plt counts votes out, then the Plt result is flagged with a *V*.

WBC Count Flag and Analytical Alarms

During the data collection for the DiffPlot, the instrument also determines the WBC count from the flow cell.

The WBC flag *DIFF-* or *DIFF+* Analytical Alarm is reported:

- If the WBC count from the flow cell exceeds the WBC count from the WBC/BASO bath by more than a predefined amount, *DIFF+* is displayed.
- If the WBC count from the flow cell is less than the WBC count from the WBC/BASO bath by more than a predefined amount, *DIFF-* is displayed.
- When a *DIFF-* or a *DIFF+* flag occurs, the WBC count and all DIFF# parameters are flagged with an *.

Note: The comparison between the WBC count from the WBC/BASO bath and the WBC count from the flow cell will not be performed when the sample is analyzed in the CBC mode or when this option is disabled in setup.

DiffPlot Flags and Analytical Alarms

When populations in the DiffPlot exceed the limits set for that region, a review (*R*) flag will occur on the DIFF parameter related to that region, and either DiffPlot and Histogram flags or Analytical Alarms will occur and indicate the area within the DiffPlot that is affected.

If the *R* flag occurs on a DIFF parameter, further investigate the result.

Twelve different flags may occur related to the position of the populations within the DiffPlot:

- *CO* (Diff Reject)
- *DB* (debris)
- *SL* (small lymphocytes)
- *SL1* (small lymphocytes 1)
- *NL* (neutrophil/lymphocyte)
- *MN* (monocyte/neutrophil)
- *UM* (upper monocyte)
- *LN* (lower neutrophil)
- *UN* (upper neutrophil)
- *NE* (neutrophil/eosinophil)
- *ATL* (atypical lymphocytes)
- *IMM* (immature cells)

See Table 9.1 for additional information.

Table 9.1 Definition of DIFF Flags

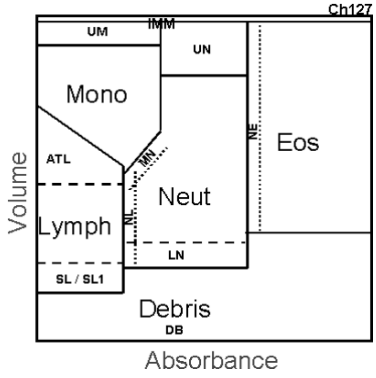
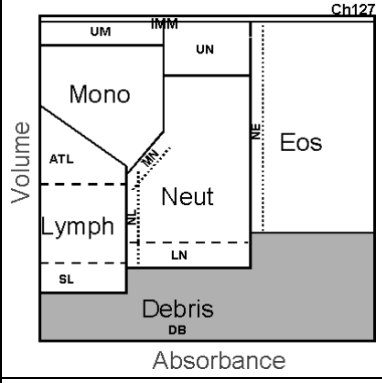
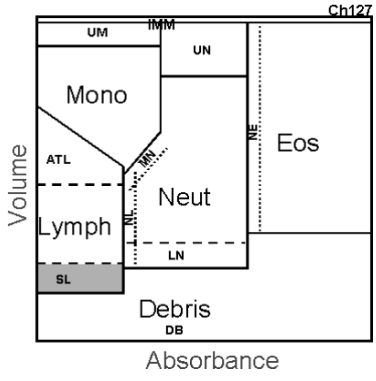
DiffPlot Region Flag	DiffPlot Region Affected	Description	Flags	Suspected Abnormalities
CO (Diff Reject)		The system detects a problem with volume and absorbance measurements in the flow cell. More than 50% of the pulses were rejected because they do not have optical pulses that meet internal criteria (100 to 300 microseconds.)	**CO** (Diff Reject) is displayed and printed in the Analytical Alarms in the Flags and Messages area.	
DB		Occurs when the number of pulses in the DB region exceeds the DB# limit. Default values: 100% or 120 particles.	**DB** (Debris) is displayed and printed in the Analytical Alarms in the Flags and Messages area.	Plt aggregates Increased Plt count RBCs resistant to lysis (stroma) NRBCs Reagent contamination
SL		Occurs when the number of particles counted in the SL region are higher than the SL# limit. Default values: 100% or 50 particles.	**R** next to: NE%, NE#, LY%, LY#, MO%, MO#, EO%, EO#, ATL%, ATL#, IMM%, IMM#. **SL** displayed and printed in Diffplot and Histogram section of the Flags and Messages area.	Small lymphocytes Plt aggregates NRBCs RBCs resistant to lysis (stroma)

Table 9.1 Definition of DIFF Flags *(Continued)*

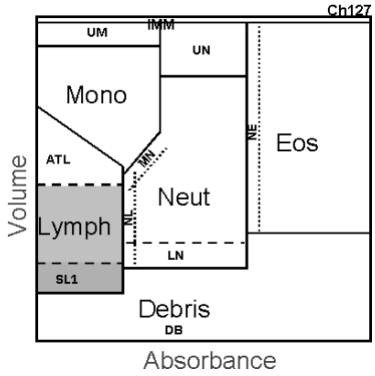
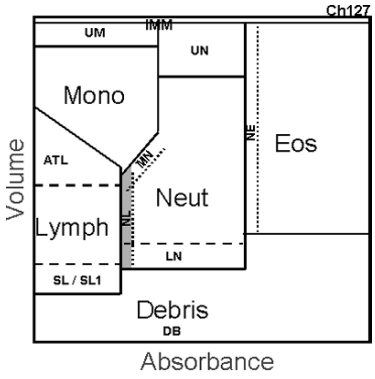
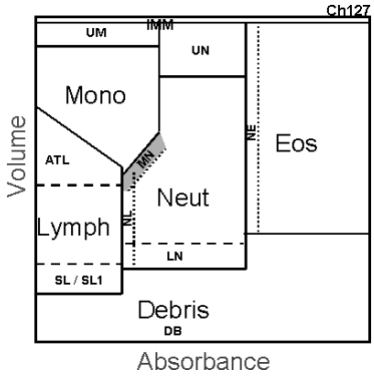
DiffPlot Region Flag	DiffPlot Region Affected	Description	Flags	Suspected Abnormalities
SL1		Occurs when the number of particles in the SL region is higher than the SL1 number limit **and** when the percentage of particles in the SL region, relative to the lymphocyte region, exceeds the SL1 percentage limit. Default values: 5% or 45 particles.	May trigger interpretive messages. NRBCs, Plt aggregates, and NRBCs plus Plt aggregates **SL1** is displayed and printed in the DiffPlot and Histogram section of the Flags and Messages area.	Plt aggregates NRBCs RBCs resistant to lysis (stroma) Small abnormal lymphocytes
NL		Occurs when the number of particles in the NL separation region is above the limits set. Default values: 3% or 120 particles.	**R** next to: NE%, NE#, LY%, and LY#. **NL** is displayed and printed in the DiffPlot and Histogram section of the Flags and Messages area.	Small Neutrophils without granules and/or slight nuclear segmentation Lymphocytes with segment nuclei Neutrophils with weak membranes (smudge/smear cells)
MN		Occurs when the number of particles in the MN separation region is above the limits set. Default values: 100% or 120 particles.	**R** next to: ATL%, ATL#, IMM%, IMM#, NE%, NE#, MO%, and MO# **MN** is displayed and printed in the DiffPlot and Histogram section of the Flags and Messages area.	Monocytes with granules or hyperbasophilic monocytes Immature neutrophils with non-segmented nuclei (band cells)

Table 9.1 Definition of DIFF Flags *(Continued)*

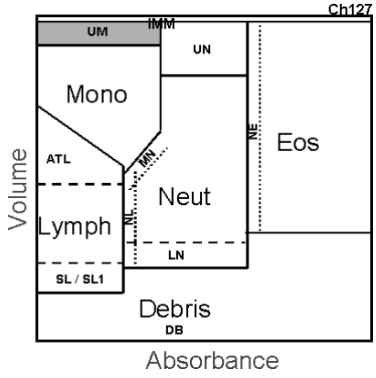
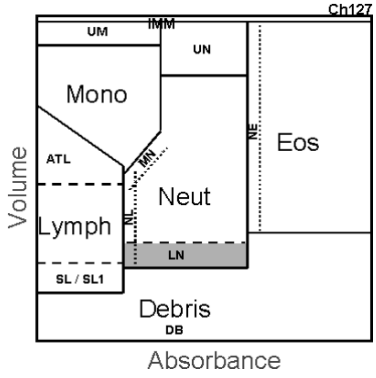
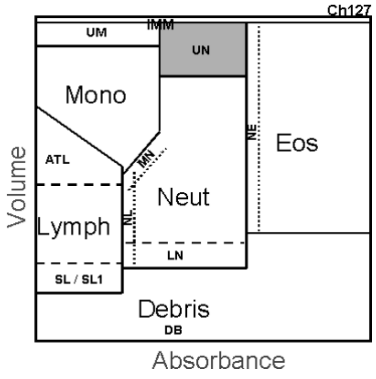
DiffPlot Region Flag	DiffPlot Region Affected	Description	Flags	Suspected Abnormalities
UM		Occurs when the number of particles in UM region is above the limits set. Default values: 1.1% or 999 particles.	**R** next to: NE%, NE#, MO%, MO#, IMM%, and IMM#. **UM** displayed and printed in the DiffPlot and Histogram section of the Flags and Messages area.	Large monocytes Hyperbasophilic monocytes Myelocytes Promyelocytes Large blasts
LN		Occurs when the number of particles in the LN region is above the limits set. Default values: 2.5% or 999 particles.	**R** next to all WBC DIFF parameters. **LN** is displayed and printed in the DiffPlot and Histogram section of the Flags and Messages area.	Neutrophil degradation due to improper storage or sample age Plt aggregates RBCs resistant to lysis (stroma) Reagent contamination
UN		Occurs when the number of particles in the UN region is above the limits set. Default values: 1.1% or 999 particles.	**R** next to: NE%, NE#, IMM%, IMM# **UN** is displayed and printed in the DiffPlot and Histogram section of the Flags and Messages area.	Large neutrophils Immature granulocytes: • Metamyelocytes • Myelocytes • Promyelocytes

Table 9.1 Definition of DIFF Flags *(Continued)*

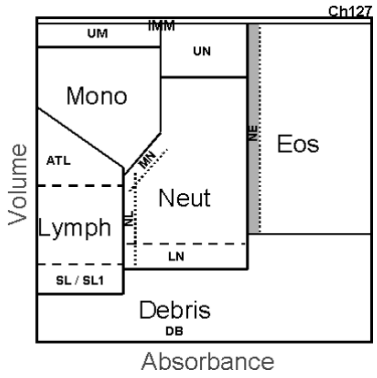
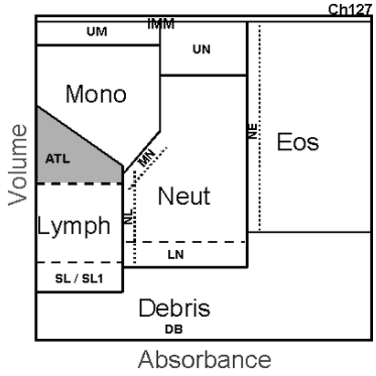
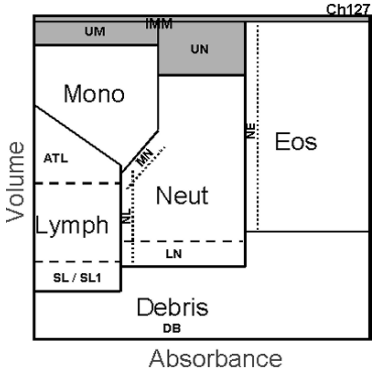
DiffPlot Region Flag	DiffPlot Region Affected	Description	Flags	Suspected Abnormalities
NE		Occurs when the number of particles the NE separation region is above the limits set. Default values: 1.1% or 60 particles.	**R** next to: IMM% and IMM#. Replaces NE%, NE#, EO%, and EO# with . . . . . **NE** is displayed and printed in the DiffPlot and Histogram section of the Flags and Messages area.	Young eosinophils Giant hypersegmented neutrophils Eosinophils with low intracytoplasmic material (agranular eosinophils)

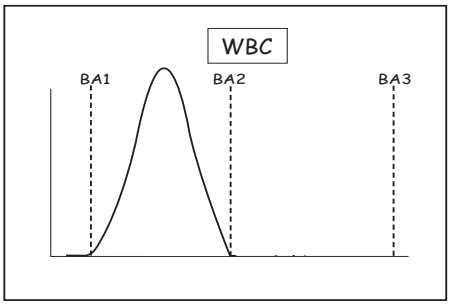
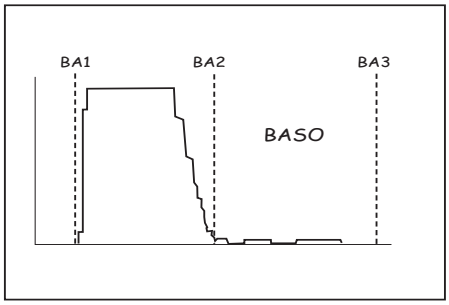
Table 9.1 Definition of DIFF Flags *(Continued)*

DiffPlot Region Flag	DiffPlot Region Affected	Description	Flags	Suspected Abnormalities
ATL		Occurs when a significantly large population is located in the ATL region. ATL flag is triggered from the Patient Limits, and the interpretive message (*Atypical Lymphocyte*) are triggered from the Action Limits. Default values: 2% or 0.2x10^9/L.	**ATL** is displayed and printed in the DiffPlot and Histogram section of the Flags and Messages area. May be displayed and printed as ATL% and ATL#.	Large lymphocytes Reactive lymphocytes Stimulated lymphocytes Plasma cells
IMM		Occurs when a significantly large population of cells is located in UN, UM, and channel 127 regions. IMM flag is triggered from the Patient Limits, and the interpretive message (*Large Immature Cell*) is triggered from the Action Limits. Default values: 2% or 0.2x10^9/L.	**IMM** is displayed and printed in the DiffPlot and Histogram section of the Flags and Messages area. May be displayed and printed as IMM% and IMM#.	Large monocytes Hyperbasophilic monocytes Myelocytes, metamyelocytes, promyelocytes Large blasts Large neutrophils

WBC/Baso Histogram Flags and Analytical Alarms

See Table 9.2.

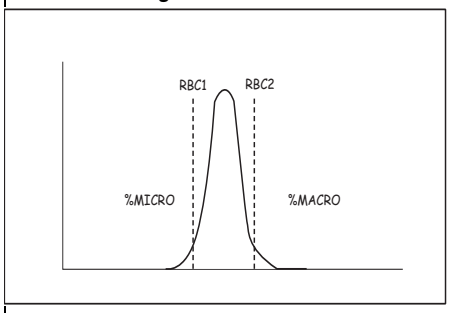
Table 9.2 WBC Histogram Flags

Histogram	Flag	Illustrations of Histogram Flags	Description
WBC/BASO	**WBC*	**Figure 9.3 WBC/BASO Histogram Flags: CBC Panel** 	Determined from the ratio of the cells counted between the 0 channel and BA1. Indicates the presence of an abnormal number of cells in comparison to leukocytes. Plt aggregates and NRBCs may be found in this region. ***WBC** is displayed and printed in the Diffplot and Histogram section of the Flags and Messages area. Default value: 3.5% or 999 particles.
	MB (Mono Baso)	**Figure 9.4 WBC/BASO Histogram Flags: CBC/DIFF Panel** 	Generated when the percentage of basophils found in the BA channel is above the percentage of the LY/MO/NE raw count found on the DIFF channel. **MB** is displayed and printed in the Diffplot and Histogram section of the Flags and Messages area.
	BASO+		If the BASO% exceeds 50%, a BASO+ flag is generated. The basophils are not taken away from the DiffPlot LY/MO/NE populations. **. . . .** is displayed and printed instead of the BA% and BA# and **BASO+** is displayed and printed in the DiffPlot and Histogram section of the Flags and Messages area.

RBC Histogram Flags

See Figure 9.3.

Table 9.3 RBC Histogram Flags

Histogram	Flag	Illustrations of Histogram Flags	Description
RBC	*MICRO and/or MACRO*	**Figure 9.5 MICRO and MACRO Regions on RBC Histogram**  	MICRO and MACRO flags are generated when the percentage of cells counted in the microcytic (MICRO) and macrocytic (MACRO) regions compared to the total number of RBCs are above the established limits set by your laboratory. See Figure 9.5. Thresholds RBC1 and RBC2 define the MICRO and MACRO regions and are calculated based on the standard deviation of a normal RBC population. **MICRO** and/or **MACRO** are displayed and printed in the DiffPlot and Histogram section of the Flags and Messages area. Default value: 5% for MICRO and 7.5% for MACRO.

Plt Histogram Flags and Analytical Alarms

See Table 9.4.

Table 9.4 Plt Histogram Flags and Analytical Alarms

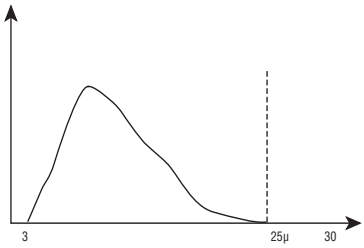
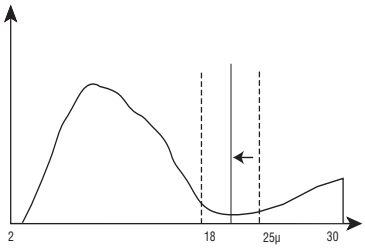
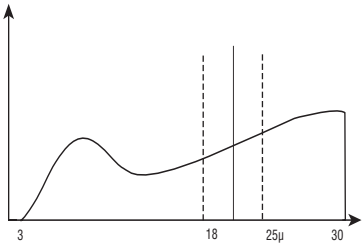
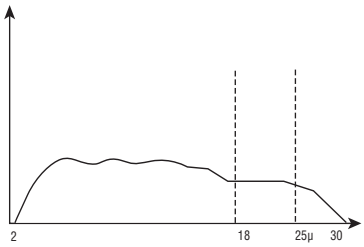
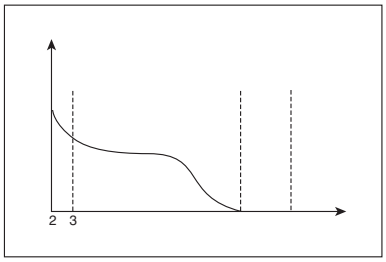
Histogram	Flag	Illustrations of Histogram Flags	Description
Plt	*MIC and SCH*	**Figure 9.6 Plt Flags**  **Figure 9.7 Mobile Threshold Positioned in the Standard Regions (Between 18 fL and 25 fL)**  **Figure 9.8 Mobile Threshold Cannot Be Positioned in the Standard Region**  **Figure 9.9 Mobile Threshold Cannot Be Positioned**  	The Plt histogram has 256 channels between 2 fL and 30 fL. A mobile threshold (at 25 fL by default) (Figure 9.6) moves according to the presence of microcytic RBCs present in the Plt analysis region. Plt flags generate when the following three conditions occur. 1. If the mobile threshold can be positioned in the standard region, between 18 fL and 25 fL, **MIC** (microcytes) is displayed and printed in the Diffplot and Histogram section of the Flags and Messages area. See Figure 9.7. The Plt result is reliable. 2. If a valley is not detected by the 18 fL threshold, the threshold is placed at the 18 fL position and **MIC** is displayed and printed in the Diffplot and Histogram section of the Flags and Messages area. If the interference is significant, the Plt count will also be flagged with **R**. 3. If the mobile threshold cannot be positioned between 18 fL and 25 fL, the threshold is placed at the 18 fL position, **SCH** (schistocytes) appears under the Diffplot and Histogram Flags heading, "Schistocytes" appears under the Interpretive Messages heading, and the Plt count is flagged with **R**. Suspected abnormalities include the presence of schistocytes and/or the presence of Plt aggregates. See Figure 9.9 The Plt result is not reliable. Verify the result by an alternative method.

Table 9.4 Plt Histogram Flags and Analytical Alarms *(Continued)*

Histogram	Flag	Illustrations of Histogram Flags	Description
Plt *(continued)*	*SCL*	**Figure 9.10 Presence of Small Cells in the 2 fL and 3fL Regions**  	**SCL** (small cells) indicates the presence of small cells in the 2fL and 3fL regions. See Figure 9.10. **SCL** appears under the Analytical Alarms heading, "Small Cells" appears under the Interpretive Messages heading and "..." appears in place of PLT and MPV parameter values. Rerun the sample and verify the results.

Patient Ranges and Action Ranges

Table 9.5 shows the four flags that can be generated based on patient ranges and action ranges.

Sample results that appear on a red background indicate an HH or LL flag. Results that appear on a yellow background indicate an H or L flag.

Table 9.5 Patient Range and Action Range Flags

Flag	Description
H	Result is above the patient limit set by your laboratory and may generate an interpretive message on the printout.
L	Result is below the patient limit set by your laboratory and may generate an interpretive message on the printout.
HH	Result is above the action limit set by your laboratory and may generate an interpretive message on the printout.
LL	Result is below the action limit set by your laboratory and may generate an interpretive message on the printout.

Interpretive Messages

ATTENTION: Interpretive messages indicate a possible pathological disorder and should be used for assisting with quickly and efficiently screening abnormal samples and for diagnosis. It is recommended that your laboratory use suitable reference methods to confirm diagnoses.

The interpretive messages print in the flag area on the patient report but only if they are enabled to print. Tables 9.6 through 9.13 list interpretive messages and triggering conditions.

If you do not enable interpretive messages to print, instrument flags must be used to identify potential abnormal sample results.

Only one DIFF interpretive message can be displayed for each DIFF parameter. The message generated from the absolute count for that parameter takes priority. For example, if a relative *LYMPHOPENIA* (LY% < LY% LL) and an absolute *LYMPHOCYTOSIS* (LY# > LY# HH) occur, only the *LYMPHOCYTOSIS* message will be displayed.

The following sections define:

- WBC Interpretive Messages,
- RBC Interpretive Messages,
- Plt Interpretive Messages, and
- Combination WBC/RBC/Plt Interpretive Messages.

Note: The DIFF + and DIFF - flags have hierarchy over any other interpretive message. Other interpretive messages will not print.

WBC Interpretive Messages

- Table 9.6 lists WBC interpretive messages from Action Ranges.
- Table 9.7 lists WBC interpretive messages from the DiffPlot.

Table 9.6 WBC Interpretive Messages from Action Ranges

Printed Message	Triggering Condition
LEUKOCYTOSIS	WBC > WBC HH
LEUKOPENIA	WBC < WBC LL
LYMPHOCYTOSIS	LY# > LY# HH, or LY% > LY% HH
LYMPHOPENIA	LY# < LY# LL, or LY% < LY% LL
NEUTROPHILIA	NE# > NE# HH, or NE% > NE% HH
NEUTROPENIA	NE# < NE# LL, or NE% < NE% LL
EOSINOPHILIA	EO# > EO# HH, or EO% > EO% HH
MONOCYTOSIS	MO# > MO# HH, or MO% > MO% HH
BASOPHILIA	BA# > BA# HH, or BA% > BA% HH
LARGE IMMATURE CELLS	IMM# > IMM# HH, or IMM% > IMM% HH
ATYPICAL LYMPHOCYTE	ATL# > ATL# HH, or ATL% > ATL% HH
MYELEMIA	NE% > NE% HH **and** IMM# > IMM# HH
BLASTS	BA# > BA# HH **and** IMM# > IMM# HH **and** UM
WBC INTERPRETATION NOT POSSIBLE	One or more analytical alarms occurred for WBC.

HH = above the action range.
LL = below the action range.

Table 9.7 WBC Interpretive Messages from DiffPlot

Message	Triggering Condition
LEFT SHIFT	MN or NL **and** UN

RBC Interpretive Messages

- Table 9.8 lists RBC interpretive messages from Action Ranges.
- Table 9.9 lists RBC interpretive messages from Flag Sensitivity.

Table 9.8 RBC Interpretive Messages from Action Ranges

Message	Triggering Condition
ANEMIA	Hgb < Hgb LL
ANISOCYTOSIS	RDW > RDW HH
HYPOCHROMIA	MCHC < MCHC LL
COLD AGGLUTININ	MCHC > MCHC HH
MICROCYTOSIS	MCV < MCV LL
MACROCYTOSIS	MCV > MCV HH
ERYTHROCYTOSIS	RBC > RBC HH
RBC INTERPRETATION NOT POSSIBLE	One or more analytical alarms occurred for RBC.

HH = above the action range.
LL = below the action range.

Table 9.9 RBC Interpretive Messages from Flag Sensitivity

Message	Triggering Condition
MICROCYTE	MICRO% > MICRO% Flag Sensitivity limit
MACROCYTE	MACRO% > MACRO% Flag Sensitivity limit

Plt Interpretive Messages

- Table 9.10 lists platelet interpretive messages from Action Ranges.
- Table 9.11 lists platelet interpretive messages from the Plt histogram.

Table 9.10 Plt Interpretive Messages from Action Ranges

Message	Triggering Condition
THROMBOCYTOSIS	Plt > Plt HH
THROMBOCYTOPENIA	Plt < Plt LL
MACROPLATELETS	MPV > 11

HH = above the action range.
LL = below the action range.

Table 9.11 Plt Interpretive Messages from the Plt Histogram

MESSAGE	Triggering Condition
MICROCYTES	Derived from Plt histogram
SCHISTOCYTE	Derived from Plt histogram

Table 9.11 Plt Interpretive Messages from the Plt Histogram *(Continued)*

MESSAGE	Triggering Condition
SMALL CELL	Derived from Plt histogram
PLT INTERPRETATION NOT POSSIBLE	One or more analytical alarms occurred for PLT.

Combination WBC/RBC/Plt Interpretive Messages

- Table 9.12 lists interpretive messages from a combination of WBC/RBC/Plt Action Ranges.
- Table 9.13 lists conditions causing *NRBCS* and *PLATELET AGGREGATES* interpretive messages.

Table 9.12 Interpretive Messages from a Combination of WBC/RBC/Plt Action Ranges

Message	Triggering Condition
PANCYTOPENIA	WBC < WBC LL **and** RBC < RBC LL **and** Plt < Plt LL

LL = below the action range.

Table 9.13 *NRBCs* and *PLATELET AGGREGATES* Interpretive Messages

Message	Triggering Condition
PLT AGGREGATES	Plt < 150x10^3/mm^3 **and** WBC voteout
	DB and PDW > 20, or DB and MPV > 10, or DB and Plt < 150x10^3/mm^3, or DB and WBC Voteout
	*WBC and PDW > 20, or *WBC and MPV > 10, or *WBC and Plt < 150x10^3/mm^3
NRBCS	SL, or SL and WBC Voteout, or *WBC and WBC Voteout, or SL1 and WBC Voteout
NRBCS & PLATELET AGGREGATES	If none of the individual conditions defined for *NRBCS* or *PLATELET AGGREGATES* occur **and** *WBC **or** SL1 **or** WBC Voteout occur.

9.4 FLAG HIERARCHY

There are three fields available to display the parameter and patient/action flags. Flags, therefore, are ranked so that a specific logic is consistently applied to determine which flags appear in which of the three available fields.

If a +, V, R, or * is generated, it will always display in the first flag field after the parameter results. In addition, the HH/LL or H/L flag can be displayed with or without the V, R, or *. If the V, R, or * is present, HH/LL or H/L displays in the second and third flag field. If the V, R, or * is not present, HH/LL or H/L displays in the second and third field.

Here are some examples:

10.3 V
5.6 *L
35.0 VHH

Replacement Flags Hierarchy

Replacement flags are ranked in the following descending order of importance:

++++

. . . .

Parameter Flags

Parameter flags are ranked in the following descending order of importance:

+
V
R
*

Patient/Action Flags Hierarchy

Patient Limits and Action Limits are ranked in the following descending order of importance:

HH/LL
H/L

9.5 IRREGULAR SAMPLE RESULTS

Erroneous results may occur if the sample is not adequately mixed before analysis. Inadequate mixing may cause either of the following typical patterns of results when compared to the expected results:

- an increase in RBC and Hgb accompanied by little change or a decrease in WBC and/or Plt

  OR

- a decrease in RBC and Hgb accompanied by little change or an increase in WBC and/or Plt

10.1 GENERAL

Calibration is a procedure to standardize the instrument by determining its deviation, if any, from calibration references and to apply any necessary correction factors.

There are two calibration modes available on this instrument:

- Auto-calibration, which uses calibration blood samples.
- Manual calibration, where known calibration factors can be directly entered.

Recommended Calibration Conditions

Beckman Coulter recommends that you perform the calibration procedure:

- At ambient operating temperature of 16°C to 34°C (61°F to 93°F).
- Using A^C•T 5diff Cal Calibrator as an alternative to whole blood.

When to Calibrate

Calibrate your instrument:

- During installation, before analyzing samples.
- After a Beckman Coulter service representative has replaced an analytical component.
- As instructed by a Beckman Coulter representative.

When to Verify Calibration

Verify calibration of your instrument:

- As required by your laboratory procedures, and as required by local or national regulations.
- When cell controls, such as A^C•T 5diff Control Plus, exceed the manufacturer's defined acceptable limits.

In the normal process of tracking data for an extended period of time, your laboratory can decide to recalibrate the instrument for a given parameter. Never adjust to a specific value based on an individual sample result.

10.2 PRE-CALIBRATION CHECKS

Before beginning calibration, it is important that you do these pre-calibration checks.

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1 Determine if there is enough reagents to complete the entire procedure.

- If not, do ***Changing Reagents***.
- If so, go to step 2.

2 Verify that the instrument has been shut down for at least 30 minutes in the past 24 hours:

- If not, do ***Extended Cleaning Procedure***.
- If so, go to step 3.

3 Do ***Heading 6.1, STARTUP***.

4 Do ***Heading 7.1, RUNNING CELL CONTROLS*** to verify calibration.

- If the control is within expected ranges, run samples. **Calibration is not necessary if the cell control is within the expected ranges**.
- If the control is not within expected ranges, do ***Heading 10.3, AUTO-CALIBRATION***.
  Calibration is required if the cell control is not within the defined limits.

10.3 AUTO-CALIBRATION

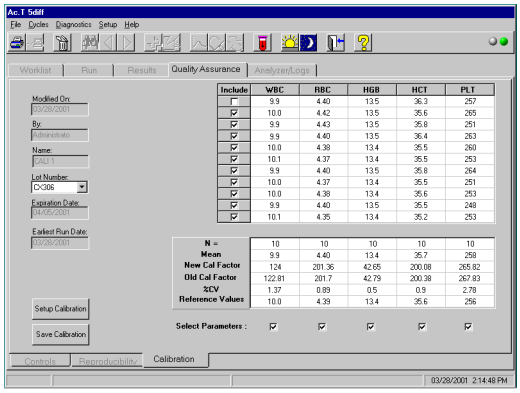
When calibration verification fails or when instructed by a Beckman Coulter representative, calibrate the instrument using this procedure.

Setup Calibration

Do this procedure to prepare the instrument to run calibration.

1 the **Quality Assurance** tab.

2 the **Calibration** tab at the bottom of the Quality Assurance window.



3 **Setup Calibration**.

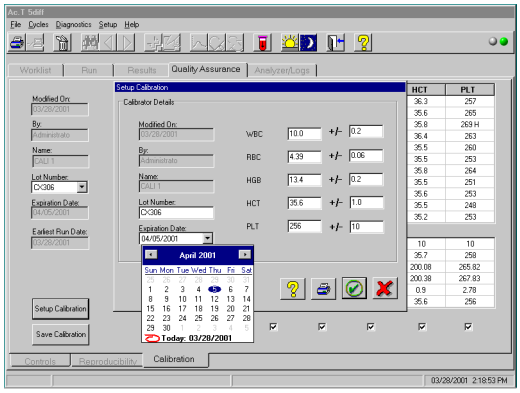
4 Enter lot number from the package insert.

5 Press Tab to move the cursor to the Expiration Date field.

6 Enter the expiration date from the calibrator's label:

a. at the Expiration Date field

b. Select the date from the calendar.



7 Enter the target values and limits from the calibrator's assay sheet:

a. Press Tab to move the cursor the value or limit you want to edit.

b. Type the number.

8 to save the input.

The Calibration screen is displayed.

If existing runs are present for this lot number, they must be deleted before proceeding.

9 **OK** to continue.

10 Verify that the lot number is correct for the calibrator to be used.

11 Do ***Running Calibration***.

Running Calibration

1 Verify that ***Setup Calibration*** was completed for the calibrator that you are using and that the Calibration screen is displayed on the Workstation monitor.

If the Calibration screen is not displayed:

a. the **Quality Assurance tab**.

b. the **Calibration** tab at the bottom of the Quality Assurance window.

c. Select the correct lot number.

d. Verify that the calibration file is empty. Delete any existing runs.

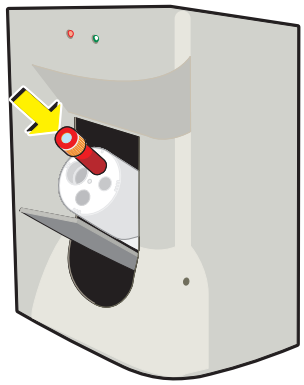
2 Prime the instrument according to the instructions on the package insert.

IMPORTANT Risk of erroneous results if the calibrator is not **thoroughly** mixed between each analysis. Mix according to the instructions in the calibrator material's package insert.

3 Prepare and mix the calibrator according to the instructions on the package insert.

4 Insert the tube correctly into:

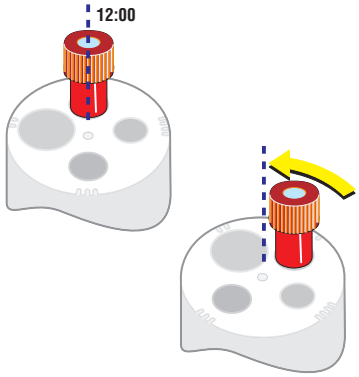
- slot #1 of Tube Holder #1, or
- slot #4 of Tube Holder #2.



IMPORTANT Risk of erroneous results if the calibrator is not positioned in the pierce position (12 o'clock) in the Analyzer.

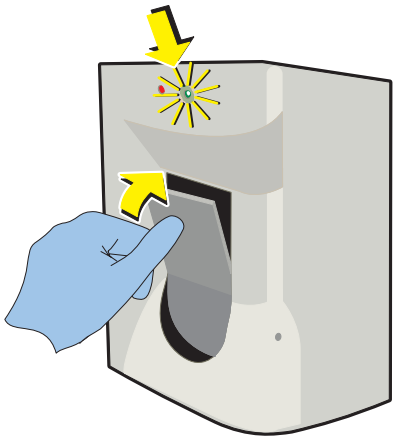
5 Ensure that the tube is in the pierce position within the tube holder.

- If the tube is in the pierce position (12:00 o'clock) within the holder, do step 6.
- If the tube is not in the pierce position within the holder, rotate the holder until the tube is in the pierce position.



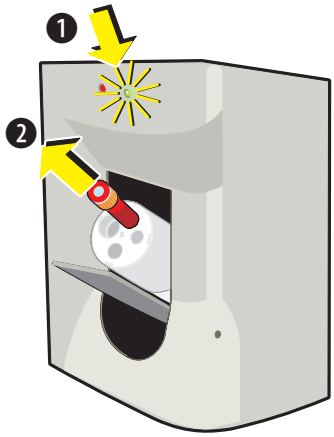
6 Close the tube holder door to begin analysis.

IMPORTANT Do not log out of the Workstation while the Analyzer is running a cycle. Logging out during an Analyzer cycle will cause problems with the Analyzer/Workstation communication.



7 When the LED is green (❶) and the tube holder door opens (❷), remove the tube.

The results are displayed.



IMPORTANT Risk of erroneous results if the calibrator is not **thoroughly** mixed between each analysis. Mix according to the instructions in the calibrator material's package insert.

8 Repeat steps 3 through 7 until at least 5, but no more than 11, calibrator samples have been analyzed.

The instrument's autocalibration module calculates statistics on these results to obtain the best possible calibration factors.

9 Review the data to determine if you want to remove one or more calibration runs from the list of results. Remember, the instrument requires 3 runs to calculate the calibration statistics.

- If you want to remove one or more calibration runs, go to step 10.
- If you do not want to remove any calibration runs, go to step 11.

Calibration passes when:

- the CV% is within the defined limits, and
- the new calibration factors are within 20% of the old calibration factors.

10 Deselect the result(s) you want to exclude:

a. the include field next to the result(s) you want to exclude.

b. The instrument recalculates the calibration statistics based on the remaining calibration results.

For additional information, see ***Interpreting Calibration Results***.

Include	WBC	RBC	HGB	HCT	PLT
☐	9.9	4.49 H	13.5	36.3	257
☑	9.7 L	4.42	13.5	35.6	265
☑	9.9	4.43	13.5	35.8	269 H
☑	9.7 L	4.49 H	13.5	36.4	263
☑	10.0	4.38	13.4	35.5	260
☑	9.8 L	4.37	13.4	35.5	253
☑	9.9	4.40	13.5	35.8	264
☑	10.0	4.37	13.4	35.5	251
☑	10.0	4.38	13.4	35.6	253
☑	9.9	4.40	13.5	35.5	248
☑	10.1	4.35	13.4	35.2	253

11 the appropriate Select parameter box to select the parameters to be calibrated.

N =	10	10	10	10	10
Mean	9.9	4.40	13.4	35.7	258
New Cal Factor	124	201.36	42.65	200.08	265.82
Old Cal Factor	122.81	201.7	42.79	200.38	267.83
%CV	1.37	0.89	0.5	0.9	2.78
Reference Values	10.0	4.39	13.4	35.6	256
Select Parameters :	☑	☑	☑	☑	☑

12 Print the calibration results:

a. .

b. Select the Calibration information you want to print.

c. Keep a copy of the calibration printout for your records.

13 Update the calibrator factors or exit without updating:

- To update the calibration factors,

  Save Calibration.

- To exit without updating, **do not**

  Save Calibration.

Note: If differences exceed the defined limits, you will have the option to calibrate, which is called "forced calibration."

14 The system automatically records the calibration information to the Calibration Log.

You can add a comment to the log. See ***Adding Comments to the Logs***.

15 Delete the calibration runs:

a. .

b. Select **Erase all rows**.

16 Do ***Heading 7.1, RUNNING CELL CONTROLS,*** to verify calibration.

Interpreting Calibration Results

The calibration screen shows:

- *N*: number of results included in the calibration statistics.
- *MEAN*: mean of the included results.
- *NEW CAL FACTOR*: what the calibration factor will be based on calculations from the new calibration data.
- *OLD CAL FACTOR*: current calibration factor.
- *%CV*: coefficient of variation of included results.
- *REFERENCE VALUES*: target values of the calibrator.

Calibration passes when:

- The CV% is within the limits defined in ***Setup Calibration***.
- The calibration factors are within the specified limits.

Forced Calibration

ATTENTION: Forced calibration should not be required. A Forced calibration is indicated by:

- the CV% is not within the defined limits, and
- the new calibration factors are within 20% of the old calibration factors.

The out of range CV% and calibration factors are highlighted on the screen.

Prior to forced calibration, which may be due to possible instrument problems and/or calibrator deterioration, contact a Beckman Coulter representative.

All “Forced” calibrations are documented in the calibration log.

10.4 MANUAL CALIBRATION FACTOR ADJUSTMENT

Do this procedure if you know the calibration factors and want to change them to achieve calibration.

If you do not know the calibration factors:

- do the procedure in ***Appendix C, MANUAL CALIBRATION***, or
- calculate the new calibration factors from data using the following formula:

  new factor = ([required value)/actual value] × current factor

---

1 the **Setup** ▸▸ **Quality Assurance**.

---

2 Type the password and .

---

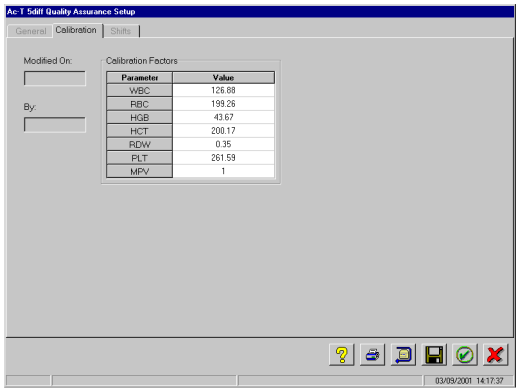
3 the **Calibration** tab at the bottom of the Quality Assurance setup window.

4 Edit the calibration factors:

a. Highlight the number to edit.

b. Edit the number.

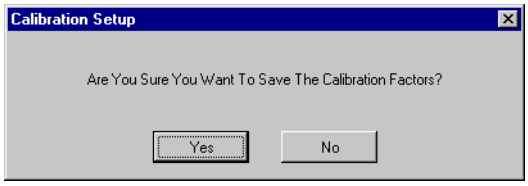
c. Repeat steps a and b for each parameter, as needed.



5 to save the changes.

6 **Yes** to save the edited calibration factors.

The entry is placed in the Calibration log and indicated as "*Forced*."



10.5 PRINTING CALIBRATION FACTORS

Do this procedure to print calibration results if you are not currently running calibration.

1 the **Setup** ▸▸ **Quality Assurance**.

2 Type the password and .

3 the **Calibration** tab at the bottom of the Quality Assurance setup window.

4 Print the calibration results:

a. .

b. Select the items you want to print.

5 Keep a copy of the calibration printout for your records.

11.1 GENERAL MAINTENANCE

This chapter details the A^{C}•T 5diff CP analyzer maintenance procedures that are your responsibility. Also included is a troubleshooting guide to help solve possible instrument problems. Failure to properly execute the maintenance procedures in this chapter may compromise instrument performance.

Perform maintenance procedures either on a time schedule or on an instrument cycle schedule. Mark the maintenance dates on your calendar.

CAUTION Incorrectly performed maintenance procedures can damage the A^{C}•T 5diff CP analyzer. Do not attempt to do any procedures not included in this manual. Contact a Beckman Coulter representative for service and maintenance beyond the scope of what is documented in this manual.

11.2 MAINTENANCE SCHEDULE

See Table 11.1.

Table 11.1 Maintenance Schedule

Maintenance Procedure	Frequency	Situation
Startup	Daily	Automatically occurs when you turn on the instrument if automatic Startup is enabled. If automatic Startup is disabled, Startup will run when you click on the icon.
Shutdown	Daily	Do ***Heading 6.4, SHUTDOWN*** to clean the instrument.
Reproducibility check	For troubleshooting or when required by your laboratory or regulatory agency.	–
Calibration verification	As needed or when required by your laboratory or regulatory agency	–
Replace reagents	When empty or when there is not enough to complete your daily workload	*Reagent(s) Low. Insufficient Reagents to Complete Daily Workload* appears
Extended cleaning	As needed	Poor instrument performance.
System Reset Cycle	After an emergency stop of the instrument or when a faulty operation has been detected	–
Replace Rinse Drain Filter	When instructed by a Beckman Coulter representative	*DRAIN SENSOR TIMEOUT* may indicate a possible filter restriction.

– indicates Not Applicable.

11.3 VIEWING THE CYCLE COUNT

The instrument counts the number of cycles run after the software is installed for:

- CBC/DIFF,
- CBC,
- Startup,
- Shutdown, and
- System Reset Cycle.

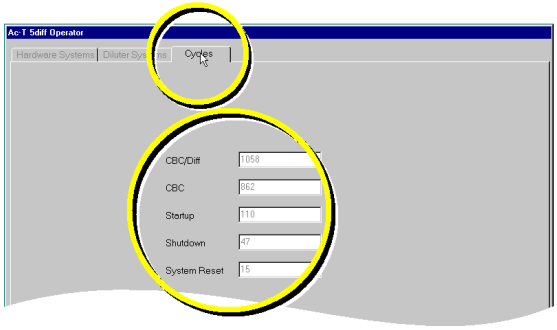
Do this procedure to review the number of cycles analyzed by the instrument.

---

1 **Diagnostics** ▸▸ **Operator**.

---

2 the **Cycles** tab.



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3 when finished.

11.4 REPRODUCIBILITY CHECK

Do this procedure:

- as required by your state or regulatory agencies, or
- for troubleshooting purposes.

1 Select a fresh, normal whole-blood sample as defined by your laboratory guidelines.

2 the **Quality Assurance** tab.

3 the **Reproducibility** tab.

4 the panel – **CBC** or **CBC/DIFF**.

IMPORTANT Risk of erroneous results if sample is not properly mixed before analysis. Mix the blood specimen gently and thoroughly before analysis according to the tube manufacturer's recommendations and your laboratory protocol.

5 Mix and analyze the sample.

IMPORTANT Do not log out of the Workstation while the Analyzer is running a cycle. Logging out during an Analyzer cycle will cause problems with the Analyzer/Workstation communication.

IMPORTANT Risk of erroneous results if sample is not properly mixed between analyses. Mix the blood specimen gently and thoroughly before each analysis according to the tube manufacturer's recommendations and your laboratory protocol.

6 Analyze samples until a minimum of an n of 10 is achieved.

7 Compare the results to the CV% limits.

Results that exceed the limits appear against a red background.

8 Repeat the runs as required.

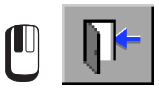
9 Contact a Beckman Coulter representative if results exceed limits.

11.5 SHUTTING DOWN WINDOWS-NT

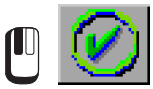
When Windows-NT shuts down, it does an automated system maintenance procedure.

Do this procedure to shutdown Windows-NT.

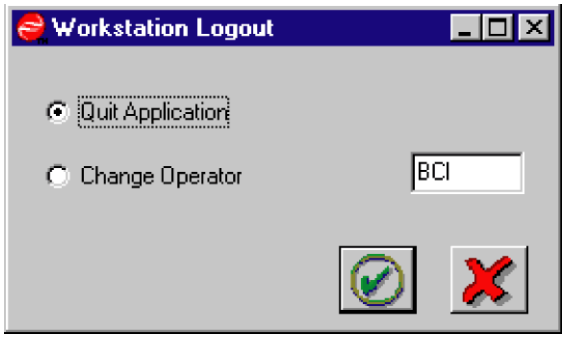
1 Log out of the Workstation:

a.  .

b. Select Quit Application.

c.  .

d. Wait while the Workstation closes its program.



2 When the Begin Logon box appears, simultaneously press Ctrl + Alt + Delete.

3 **Shut Down**.

4 Verify that only **Shut Down** is selected.

5 **OK**.

The Workstation automatically shuts down and informs you that the system is ready to be powered off or restarted.

11.6 CLEANING PROCEDURES

WARNING Risk of biohazardous conditions. Utilize appropriate barrier protection when performing these procedures, as the instrument may contain biohazardous material.

Cleaning the Tube Holder

CAUTION Risk of damage to tube holder if it is exposed to temperatures of 70°C (158°F) or higher. Do not heat sterilize the tube holder or subject it to temperatures of 70°C (158°F) or higher.

Clean the tube holder with a damp cloth and distilled water. You can also use a 1% to 2% chlorine solution made from distilled water and high-quality, fragrance-free, gel-free bleach (5 to 6% solution of sodium hypochlorite-available chlorine).

Cleaning the Outside of the Instrument

Clean the outside of the instrument with a damp cloth and distilled water to prevent the buildup of corrosive deposits. Pay particular attention to the sampling probe area. Clean up spills promptly.

Cleaning the Inside of the Instrument

If corrosive deposits are evident, clean the inside of the instrument with a damp cloth and distilled water. Be careful not to wipe contaminants into the baths.

Extended Cleaning Procedure

Do this procedure to clean the baths with a 1% to 2% solution of sodium hypochlorite:

- If you suspect a clog or fibrin.
- After doing the ***Cleaning the Baths and Lower Rinse Block*** procedure.
- When directed by a Beckman Coulter representative.

Supplies needed:

- ❑ One 5mL syringe
- ❑ 50mL of a 1 to 2% chlorine solution produced from high-quality, fragrance-free, gel-free bleach (5 to 6% solution of sodium hypochlorite-available chlorine)

---

1 Prepare a 1% to 2% chlorine solution using high-quality, fragrance-free, gel-free bleach (5 to 6% solution of sodium hypochlorite-available chlorine).

For example:

- If using 4% bleach, dilute with an equal part of distilled water.
- If using 10% to 12% bleach, dilute by adding 10 parts distilled water to 1 part of the 10% to 12% high-quality, fragrance-free sodium hypochlorite.

2 **Cycles** ▸▸ **Extended Cleaning**.

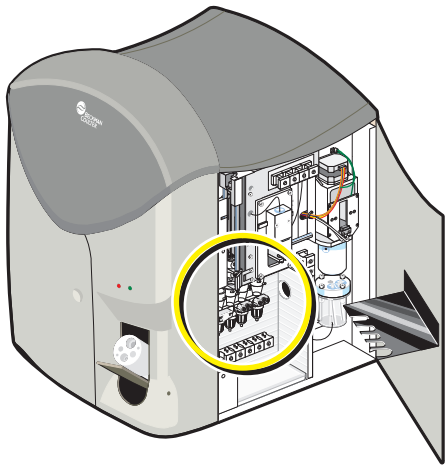
Note: You can also access **Extended Cleaning** through the Operator Diagnostics options:

- **Diagnostics** ▸▸ **Operator**.
- the **Diluter Systems** tab.
- the **Cleaning Cycles** tab.
- **Extended Cleaning**.

3 Open the right side door.

a. Use the door key to loosen the two screws on the right side door.

b. Swing open the door.

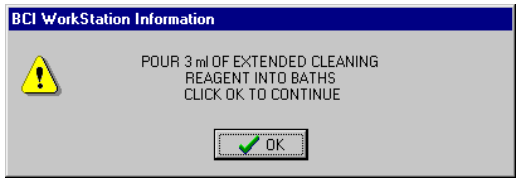


4 **Extended Cleaning**.

You Have Requested to Run Extended Cleaning Cycle. Continue? appears.

5 **OK** to initiate the cycle.

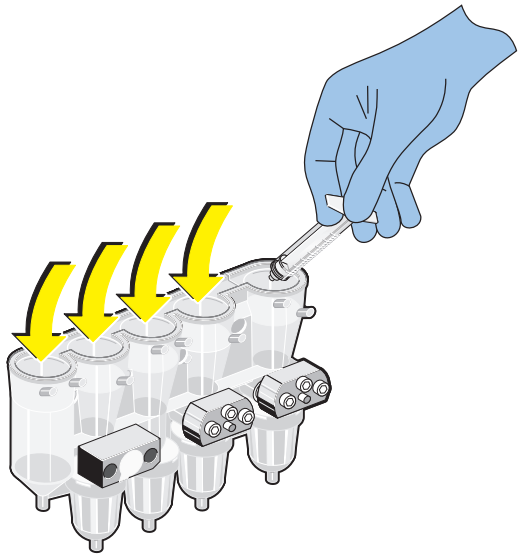
6 After about 1 minute, you will be prompted to pour the cleaning reagent (1% to 2% chlorine solution) into the baths.



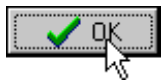
Note: Do not **OK** until after you pour the cleaning reagent into the baths.

WARNING Risk of contamination. If you do not properly shield yourself while decontaminating the instrument, you may become contaminated. To prevent possible biological contamination, you must use appropriate barrier protections (safety glasses, a lab coat, gloves, and so forth) when performing this procedure.

7 Dispense 3 mL of the 1% to 2% chlorine solution into each bath.



8 **OK** to continue.



9 Close the right side door and secure the two screws with the door key.

10 .

Allow the instrument to complete the cleaning procedure. (**Note**: It takes about 5 minutes for the cycle to complete.)

The system will automatically flush to remove the chlorine solution that you dispensed in step 7.

Auto-Clean

An auto-clean (automatic cleaning) is performed by the instrument after a specified number of samples are analyzed. You can set the frequency from 1 to 75 (75 is the default). See ***Changing the Auto-Clean Frequency Setting***.

Shutdown

At the end of each day, do Shutdown to

- cleanse the instrument,
- shut down the computer,
- and power off the analyzer and PC.

See ***Heading 6.4, SHUTDOWN*** for the procedure.

Cleaning the Baths and Lower Rinse Block

Do this procedure as needed.

Tools/Supplies Needed:

- ❑ 25mL of a 1% to 2% chlorine solution produced from high-quality, fragrance-free, gel-free bleach (5 to 6% solution of sodium hypochlorite-available chlorine).
  - ▸ If using 4% high-quality, fragrance-free sodium hypochlorite, dilute with an equal part of distilled water.
  - ▸ If using 10% to 12% high-quality, fragrance-free sodium hypochlorite, dilute by adding 10 parts distilled water to 1 part of the sodium hypochlorite.
- ❑ Lint-free wipes
- ❑ Fabric-tipped applicators

Note: The ***Extended Cleaning Procedure*** must be performed after this procedure.

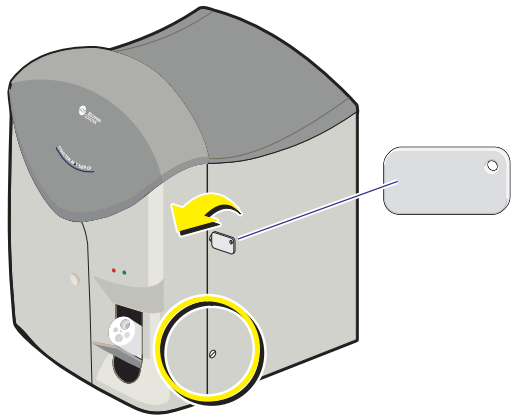
1 Power down the system as instructed in **Power Down the System** in Chapter 5.

2 Disconnect the power cord from the back of the analyzer.

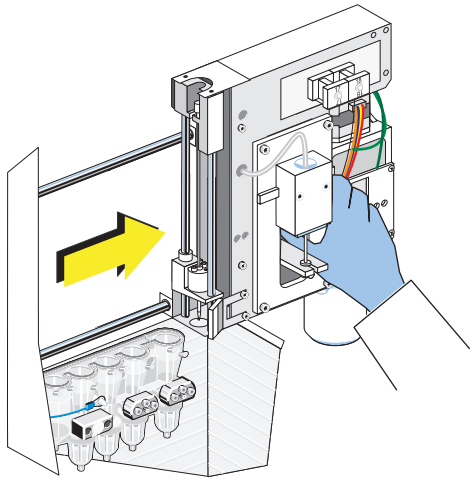
3 Open the right side door.

a. Use the door key to loosen the two screws on the right side door.

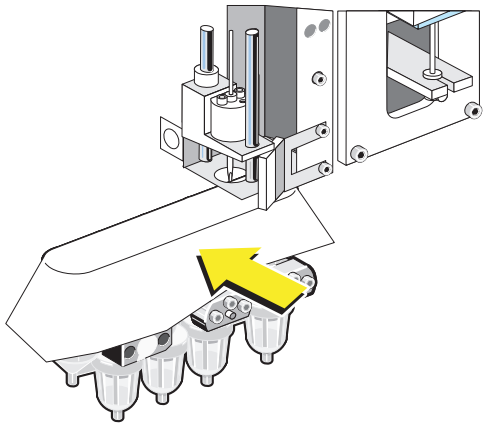
b. Swing open the door.



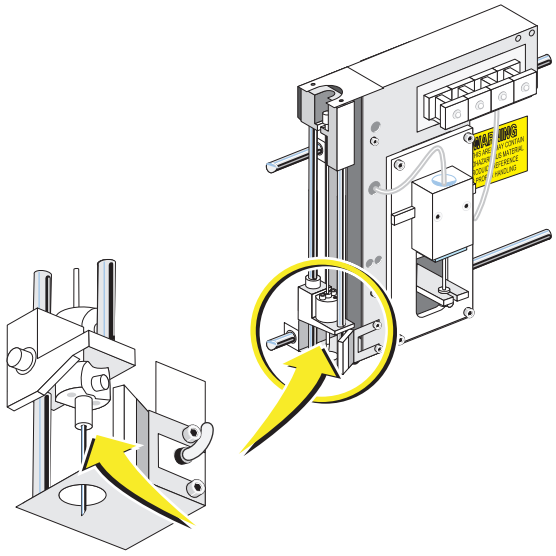
4 Gently move the traverse assembly towards the rear of the instrument.



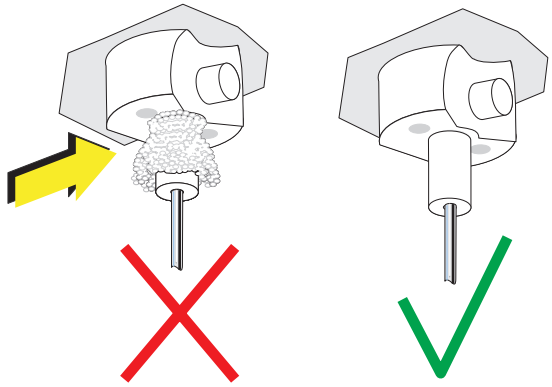
5 Cover the baths with a lint-free wipe. This will protect them from falling contaminants.



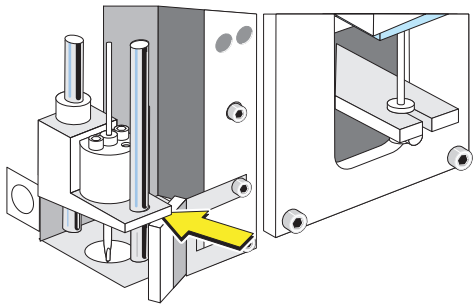
6 Locate the lower rinse block.



7 Inspect the lower rinse block.

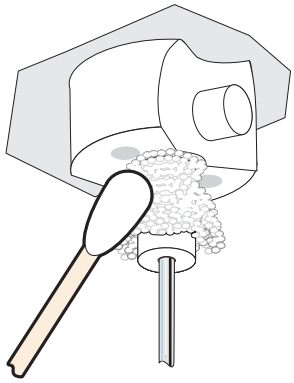


8 Note the location of the white safety block. Be careful not to move it from under the needle carriage as you do the rest of this procedure.

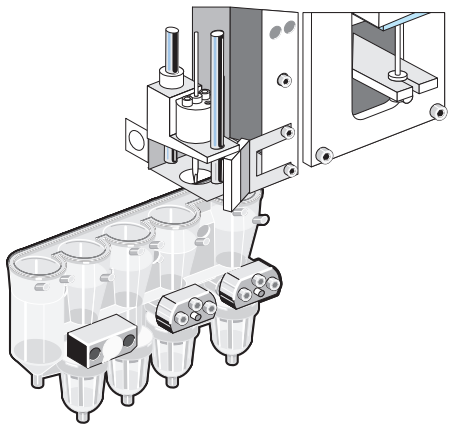


9 Apply a liberal amount of the cleaning solution to a fabric-tipped applicator and clean the lower rinse block. Repeat with additional applicators until the rinse block is clean.

CAUTION Be careful not to move the white safety block from under the needle carriage.



10 Remove the lint-free wipe from the baths.

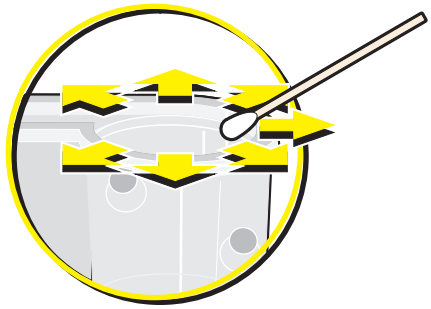


11 Apply a liberal amount of the cleaning solution to another fabric-tipped applicator.

ATTENTION: Do not wipe contaminants into the baths.

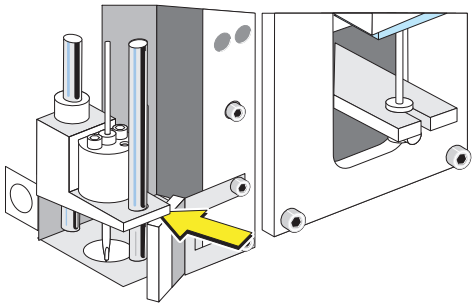
12 Use the applicator to clean the top of a bath:

With an outward motion, slowly and carefully wipe around the top of the bath.

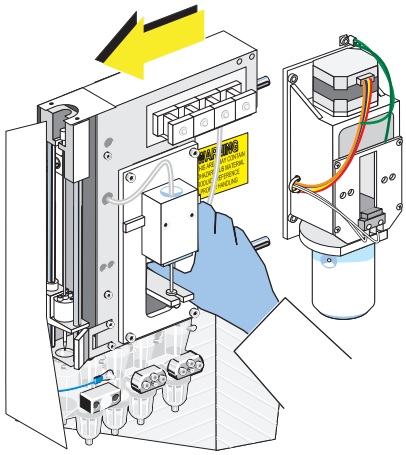


13 Using a new applicator for each bath, repeat steps 11 and 12 until all baths are cleaned.

14 Verify that the white safety block is in the correct position



15 Gently move the traverse assembly to the front of the instrument until it stops.



16 Close the right side door and secure the two screws with the door key.

17 Reconnect the power cord to the rear of the analyzer.

18 Power up the system as instructed in ***Power Up the System*** in Chapter 5.

19 To remove any debris or contaminants from the baths, do the ***Extended Cleaning Procedure***.

20 Cycle a sample with known results to verify instrument performance.

System Cleaning

This procedure may be performed prior to performing procedures that involve the handling of components that have contacted blood.

Tools/Supplies Needed:

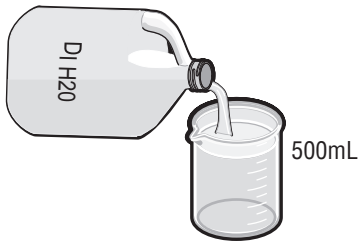
- ❑ 500mL of a 1% to 2% chlorine solution produced from high-quality, fragrance-free, gel-free bleach (5 to 6% solution of sodium hypochlorite-available chlorine)
- ❑ Deionized water
- ❑ Absorbent paper
- ❑ Distilled water
- ❑ 2 containers (such as beakers or flasks) that can each hold more than 500mL of liquid and can be placed in front of the reagent compartment when the door is open

---

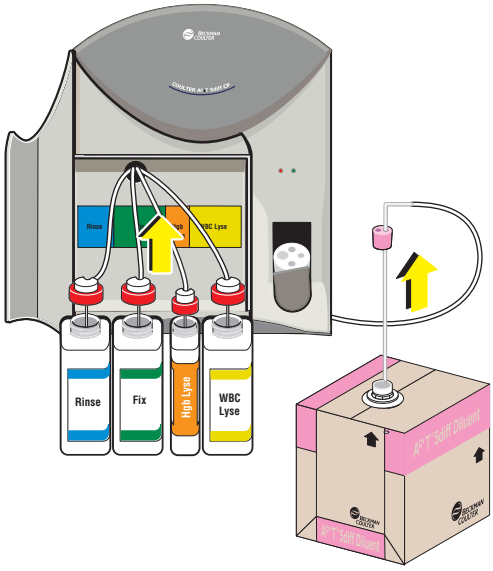
1 Do ***Extended Cleaning Procedure***.

---

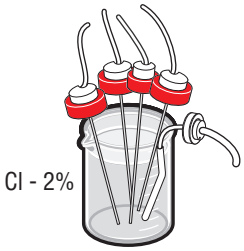
2 Pour 500mL of distilled water into the other container.



3 Remove all reagent pickup tube assemblies from their containers, including Diluent.



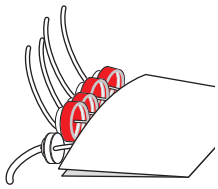
4 Place all reagent pickup tube assemblies in the chlorine solution.



5 Prime all reagents as instructed in ***Priming the Reagents***.

Chlorine solution will now be pulled into the instrument through the reagent pickup tubes.

6 When priming is complete, remove the reagent pickup tube assemblies from the chlorine solution, and wrap the tubes in absorbent paper.

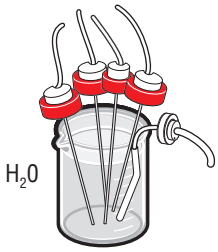


7 Prime all reagents as instructed in ***Priming the Reagents***.

The chlorine solution will now be drained from the system.

8 Place the container with the distilled water in front of the reagent compartment.

9 Place all pickup tube assemblies into the container.



10 Prime all reagents as instructed in ***Priming the Reagents***.

The distilled water will now be pulled in to rinse the system.

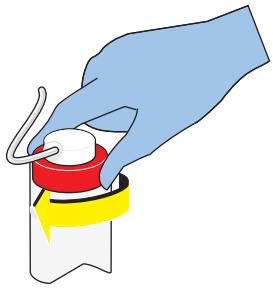
11 Run a blank cycle.

12 Remove all pickup tubes from the container.

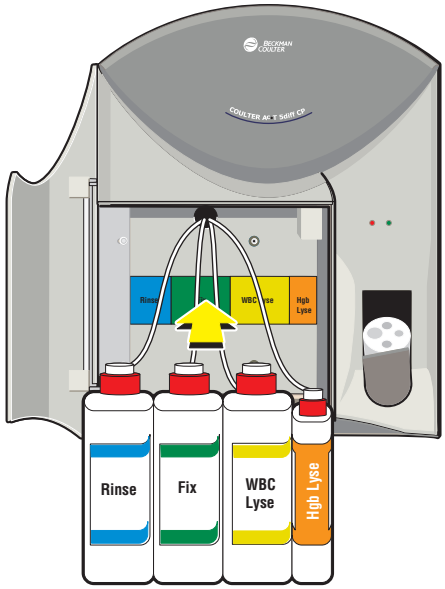
13 Repeat step 10.

14 Reconnect the reagent pickup tube assemblies to their respective containers.

15 Be sure each pickup tube cap is properly tightened.



16 Place the reagent containers in their respective locations.



17 Prime all reagents as instructed in ***Priming the Reagents***.

18 Inspect the reagent lines to ensure there are no air bubbles present.

If air bubbles are present, repeat step 17.

19 Power down the system as instructed in ***Power Down the System*** under ***Heading 5.2, POWER UP/POWER DOWN***.

20 Power up the system as instructed in ***Power Up the System*** under ***Heading 5.2, POWER UP/POWER DOWN***.

11.7 SYSTEM RESET CYCLE

The System Reset Cycle performs a general rinse, draining, and initialization of mechanical assemblies.

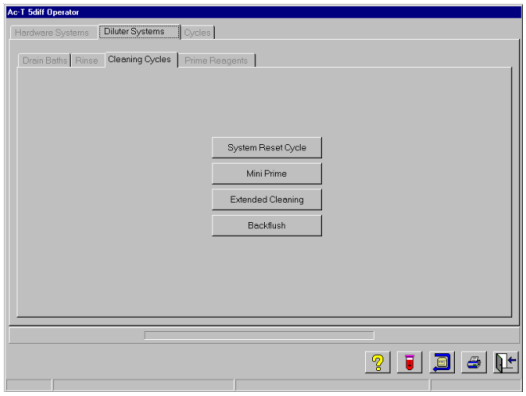
Do a System Reset Cycle:

- if the instrument halts due to error,
- after an emergency stop of the instrument,
- when the instrument reports a faulty operation, or
- when prompted by the instrument.

1 **Cycles** ▸▸ **System Reset Cycle**.

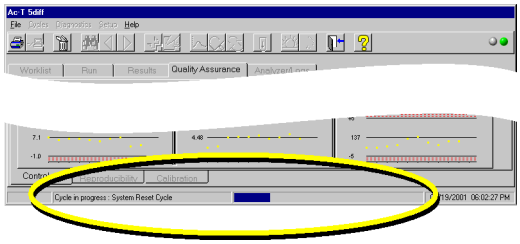
Note: You can also access **System Reset Cycle** through the Operator Diagnostics options:

- **Diagnostics** ▸▸ **Operator**.
- the **Diluter Systems** tab.
- the **Cleaning Cycles** tab.
- **System Reset Cycle**.



2 Allow the system reset cycle to finish (about 2 minutes).

The progress bar shows the status of the operation.



Mini Prime

Mini Prime primes all the reagent lines.

Do this procedure:

- If the system has been idle between 2 and 4 hours.
- If the Analyzer has been turned off then on again.

---

1 **Cycles** ▸▸ **Mini Prime**.

Note: You can also access **Mini Prime** from within the Operator Diagnostics options:

- **Diagnostics** ▸▸ **Operator**.
- the **Diluter Systems** tab.
- the **Cleaning Cycles** tab.
- **Mini Prime**.

---

2 Allow the Mini Prime to finish (about 2 minutes).

---

3 Cycle a sample with known results to verify instrument performance.

---

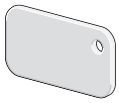
4 Resume normal operation

11.8 REPLACING THE RINSE BATH DRAIN FILTER

Purpose

Do this procedure when instructed by a Beckman Coulter representative.

Tools/Supplies Needed

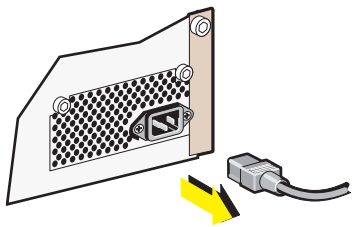
-  (door key)
- (filter assembly)

Note: For any part that you use from your spare parts kit, be sure to record the part number for reordering.

Procedure

1 Power down the system as instructed in **Power Down the System** in Chapter 5.

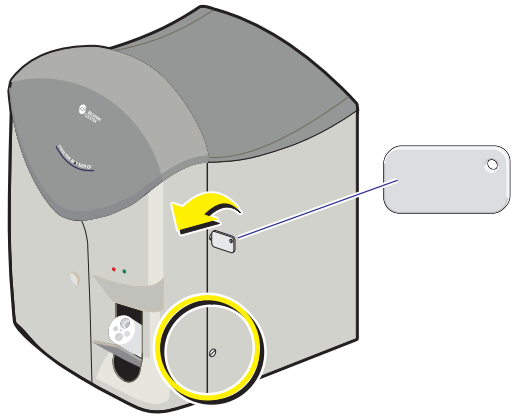
2 Disconnect the power cord from the back of the analyzer.



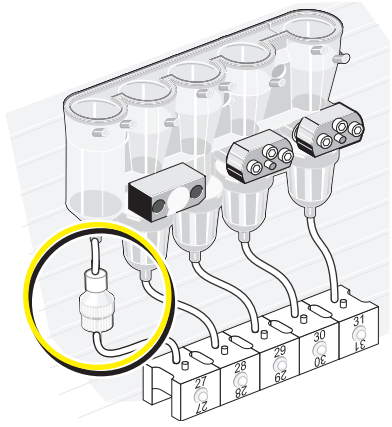
3 Open the right side door.

a. Use the door key to loosen the two screws on the right side door.

b. Swing open the door.



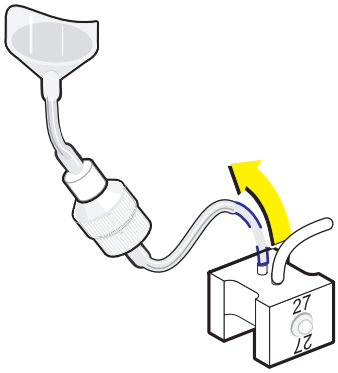
4 Locate the filter between the rinse bath and valve 27.



IMPORTANT Risk of leakage from the rinse bath filter if the gasket is lost. The rinse bath filter has an upper half and a lower half. When replacing the filter, keep the new filter together so that the small gasket inside the filter stays in place.

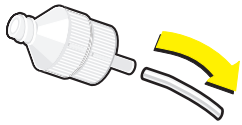
5 Remove the rinse bath filter:

a. Remove the tubing from of the rear port of valve 27.



b. Grasp the upper half of the filter and twist it until it is completely loosened from the top fitting.

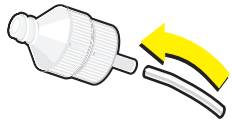
c. Remove the tubing from the bottom of the filter.



6 Properly dispose of the old rinse bath filter.

7 Install the new rinse bath filter:

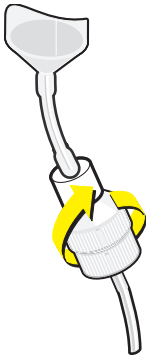
a. Connect the existing tubing to the bottom of the new filter.



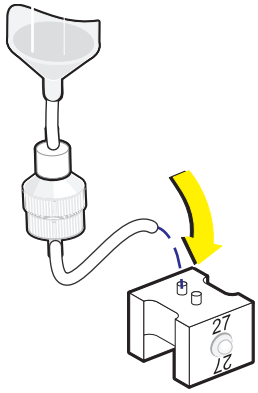
b. Grasp the upper half of filter and insert the end into the fitting.

c. Secure the filter by turning as needed.

d. Connect the tubing on the bottom of the filter to the rear port of valve 27.



e. Push the tubing down over the fitting till it is secure.



8 Close the right side door.

9 Reconnect the power cord to the rear of the analyzer.

10 Power up the system as instructed in **Power Up the System** in Chapter 5.

11 Cycle a sample with known results to verify instrument performance.

12 After the cycle is complete, open the right side door to confirm there are no leaks and that the rinse bath is empty.

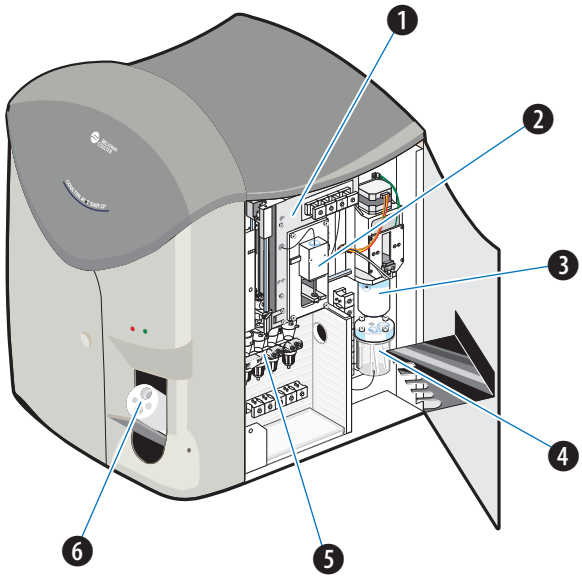
13 Close the right side door, secure the two screws using the door key, and resume normal operation.

11.9 COMPONENT LOCATIONS

See the following figures for component locations:

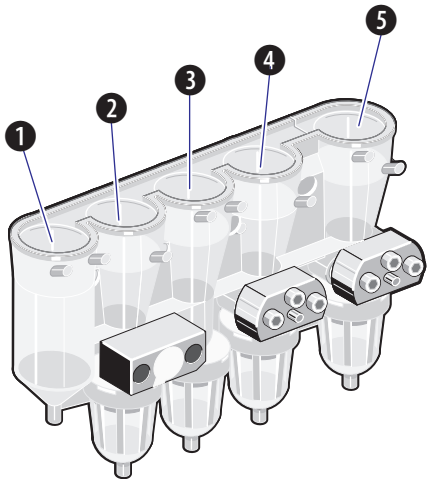
- Figure 11.1, View of the Pneumatics Area,
- Figure 11.2, Bath Assembly,
- Figure 11.3, View Behind Main Card (Left Side), and
- Figure 11.4, Main Card.
- Figure 11.5, Computer Workstation: Front View
- Figure 11.6, Computer Workstation: Back View

Figure 11.1 View of the Pneumatics Area



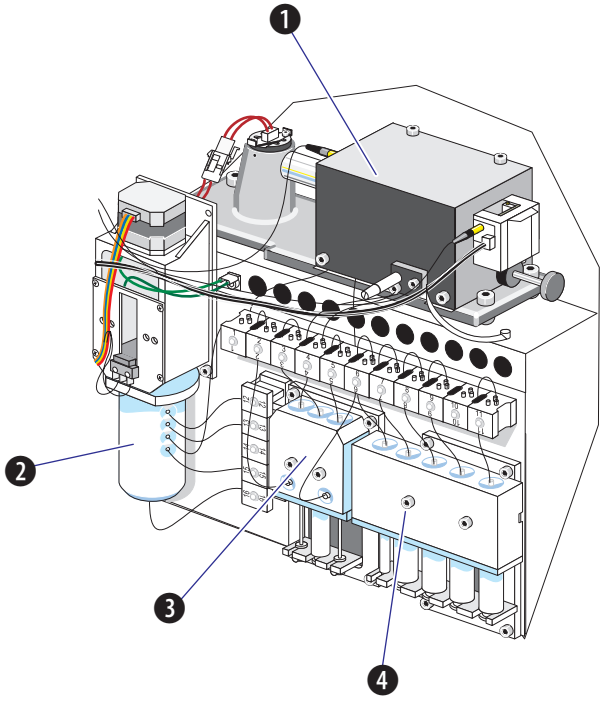
1. Traverse assembly:
   - ensures probe positioning for the sample stages and distribution, and
   - supports the sampling syringe.
2. Sampling syringe:
   - aspirates sample,
   - distributes portions of the specimen into the dilution baths, and
   - takes the sample from the first dilution and distributes it into the RBC bath.
3. Waste syringe
   - drains the baths,
   - bubbles the mixtures, and
   - transfers the DIFF specimen to the flow cell.
4. Diluent reservoir:
   - holds the necessary diluent for an analysis cycle,
   - prevents diluent degassing as it is being aspirated by the syringes, and
   - is vacuum filled by the count syringe.
5. Bath assembly: receives the different rinsings and dilutions,
6. Tube holder: holds the tubes/vials.

Figure 11.2 Bath Assembly



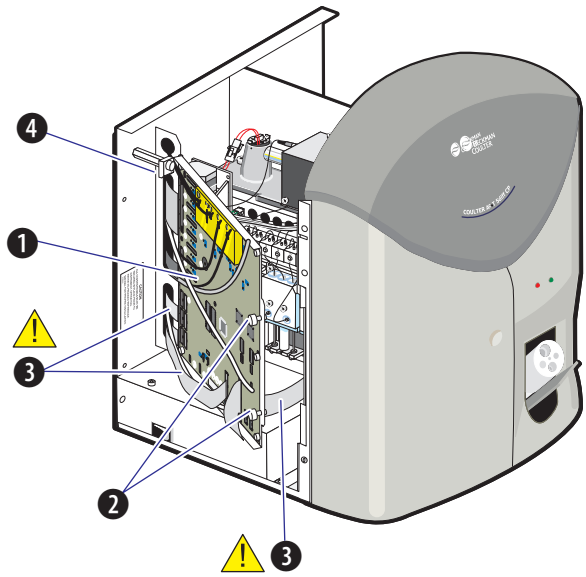
1. Rinse bath
2. First Dilution/Hgb bath
3. DIFF bath
4. RBC bath
5. WBC/BASO bath

Figure 11.3 View Behind Main Card (Left Side)



1. Optical bench: ensures the support and adjustment of the flow cell, lamp, and optical and electronic elements.
2. Count syringe
   - ensures the vacuum for the WBC and BASO counts,
   - ensures the vacuum for the RBC and Plt counts, and
   - ensures the vacuum for filling the diluent reservoir with diluent.
3. DIFF syringe assembly
   - injects the diluted sample into the flow cell, and
   - injects the interior and exterior sheath into the flow cell.
4. Reagent syringe assembly
   - ensures correct reagent delivery:
     - Lysing reagent for Hgb (A^C•T 5diff Hgb Lyse)
     - Rinsing reagent (A^C•T 5diff Rinse)
     - Lysing reagent for DIFF (A^C•T 5diff Fix)
     - Lysing reagent for WBC/BASO (A^C•T 5diff WBC Lyse)
     - Diluent (A^C•T 5diff Diluent)

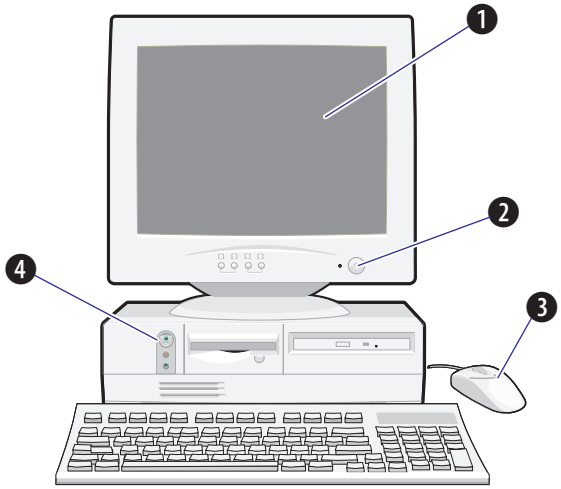
Figure 11.4 Main Card



ATTENTION: When opening the Main card support panel, use care not to disconnect or damage the electric cables.

1. Main card:
   - amplifies, processes, and counts the resistive signals and DIFF optical signals, the RBC signal, the Plt signal, and the WBC/BASO signal,
   - measures hemoglobin,
   - controls the motorized components,
   - processes data and calculates results, and
   - communicates with the Workstation.
2. Screws that secure the Main card to the frame.
3. Cables that must not be pinched or damaged when the Main card door is opened.
4. Latch that holds Main card open.

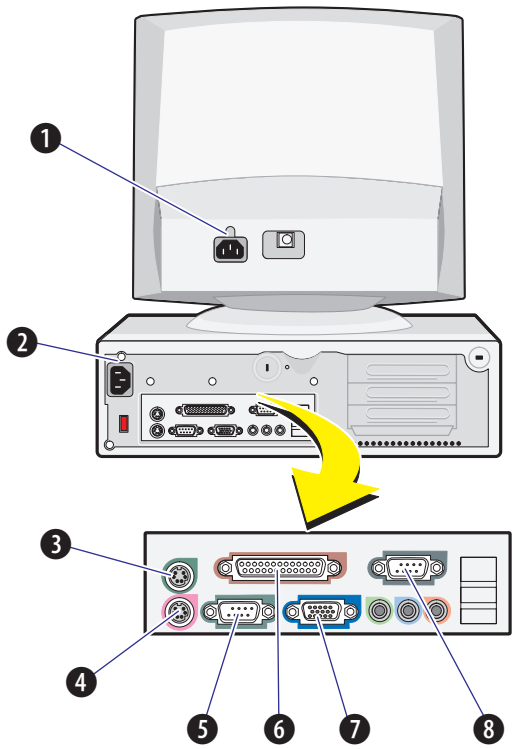
Figure 11.5 Computer Workstation: Front View



1. Monitor
2. Monitor power ON/OFF switch
3. Mouse
4. Workstation power ON/OFF switch

Note: Your configuration may vary from that shown here.

Figure 11.6 Computer Workstation: Back View



1. Monitor power cord connection
2. PC power cord connection
3. Mouse connection
4. Keyboard connection
5. Analyzer connection
6. Printer connection
7. Monitor connection
8. Host communications connector

Note: Your configuration may vary from that shown here

11.10 SYSTEM TROUBLESHOOTING PROCEDURES

Diluter System

Backflush

The backflush feature pushes pressure through the rear of the apertures to remove blockages.

Do this procedure if you suspect blocked apertures.

---

1 **Cycles** ▸▸ **Backflush**.

Note: You can also access **Backflush** through the Operator Diagnostics options:

- **Diagnostics** ▸▸ **Operator**.
- the **Diluter Systems** tab.
- the **Cleaning Cycles** tab.
- **Backflush**.

---

2 Allow the backflush cycle to complete (about 1 minute).

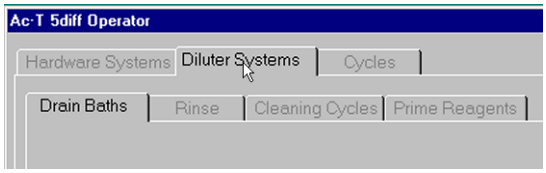
Rinse Baths and Flow Cell

Do this to rinse the instrument's baths and/or flow cell with A^{C}•T 5diff Diluent.

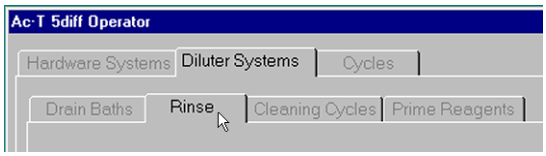
- Rinse the baths if you have excessive flagging on CBC parameters.
- Rinse the flow cell to remove bubbles from the flow cell or if you have excessive flagging on DIFF parameters.

1 **Diagnostics** ▸▸ **Operator**.

2 the **Diluter Systems** tab.



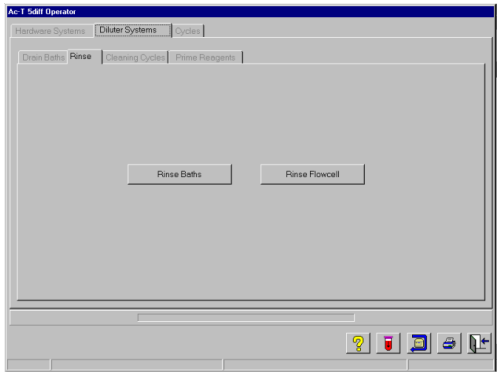
3 the **Rinse** tab.



4 **Rinse Baths** or **Rinse Flowcell**.

The instrument rinses the selected component.

Note: Rinse Baths finishes in about 2 minutes. Rinse Flowcell finishes in about 1 minute.

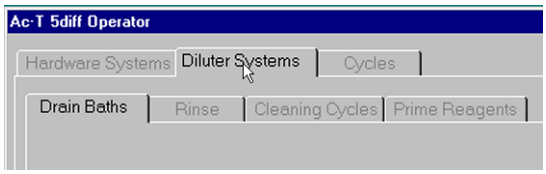


Draining the Baths and/or the Diluent Reservoir

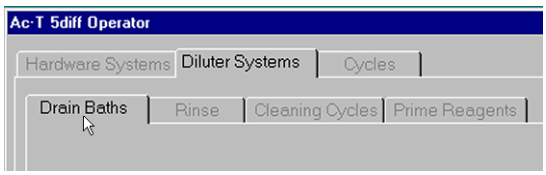
Do this procedure if you suspect a draining problem with the baths and/or the diluent reservoir.

1 **Diagnostics** ▸▸ **Operator**.

2 the **Diluter Systems** tab.

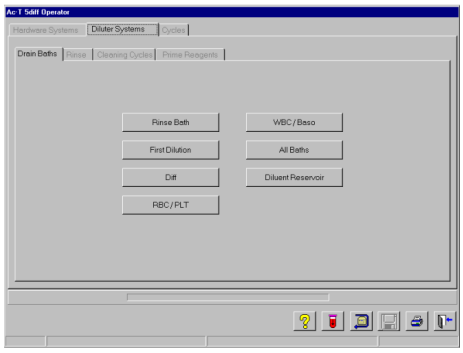


3 the **Drain Baths** tab.



4 one of the following options:

- **Rinse Bath**
- **First Dilution**
- **DIFF**
- **RBC/PLT**
- **WBC/BASO**
- **All Baths**
- **Diluent Reservoir**.



Note: If you **All Baths** or **Diluent Reservoir**, a status bar appears to show progress. For the other options, the red LED illuminates when the function is in progress.

5 If you selected **Diluent Reservoir**, **OK** to continue.

IMPORTANT Risk of erroneous results if you do not prime the Diluent after draining the Diluent reservoir. Reprime the Diluent.

6 After the Diluent Reservoir is drained, prime the Diluent:

a. **Diagnostics** ▸▸ **Operator**.

b. the **Diluter Systems** tab.

c. the **Prime Reagents** tab.

d. **Diluent**.

Hardware Systems

The information in this section includes:

- Hardware Reset,
- Sampling Probe Test,
- Traverse Test,
- Sampling Syringe Test,
- Draining Syringe Test,
- Counting Syringe Test,
- Flow Cell Syringes Test,
- Dilution Syringe Test,
- Piercing Mechanism Test
- Valves Test,
- Traverse Service Position, and
- Parking the Syringes.

Hardware Reset

Hardware Reset initializes the mechanical assemblies and resets instrument components, such as motors and valves, to a normal or “home” position.

---

1 **Diagnostics** ▸▸ **Operator**.

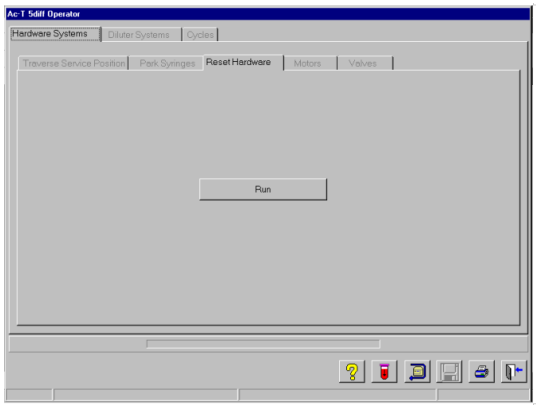
---

2 the **Hardware Systems** tab.

3 the **Reset Hardware** tab.

4 **Run**.

The instrument resets components to a "home" position.

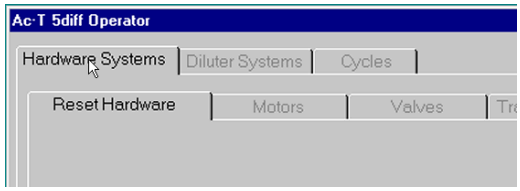


Sampling Probe Test

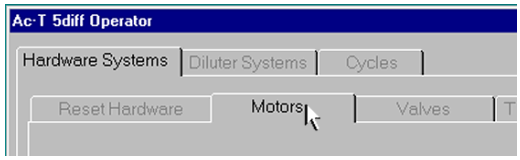
Do this procedure to test the sampling probe motor and reset the sampling probe to its "home" position.

1 **Diagnostics** ▸▸ **Operator**.

2 the **Hardware Systems** tab.



3 the **Motors** tab.



4 **Sampling Probe**.

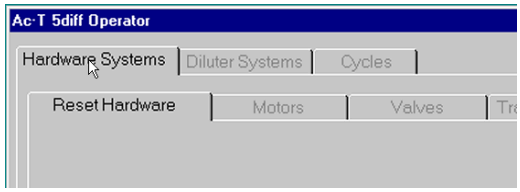
The instrument exercises the sampling probe motor resets the sampling probe to its "home" position.

Traverse Test

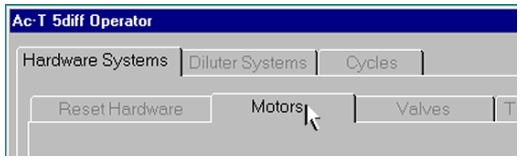
Do this procedure to test the traverse assembly motor and reset the traverse assembly to its "home" position.

1 **Diagnostics** ▸▸ **Operator**.

2 the **Hardware Systems** tab.



3 the **Motors** tab.



4 **Traverse**.

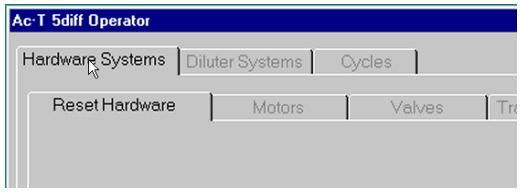
The instrument exercises the traverse motor resets the traverse assembly to its "home" position.

Sampling Syringe Test

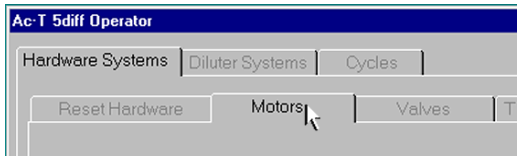
Do this procedure to test the sampling syringe motor and reset the sampling syringe to its "home" position.

1 **Diagnostics** ▸▸ **Operator**.

2 the **Hardware Systems** tab.

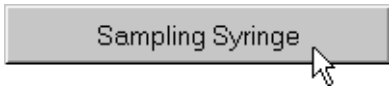


3 the **Motors** tab.



4 **Sampling Syringe**.

The instrument exercises the sampling syringe motor and resets the syringe to its "home" position.

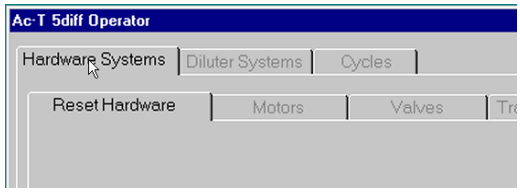


Draining Syringe Test

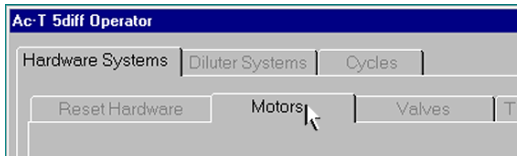
Do this procedure to test the draining syringe motor and reset the draining syringe to its "home" position.

1 **Diagnostics** ▸▸ **Operator**.

2 the **Hardware Systems** tab.

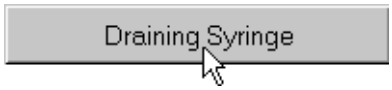


3 the **Motors** tab.



4 **Draining Syringe**.

The instrument exercises the draining syringe motor and resets the draining syringe to its "home" position.

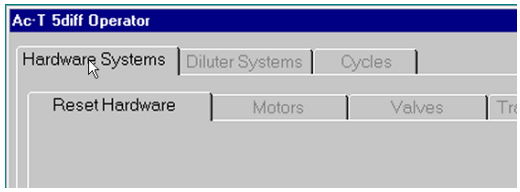


Counting Syringe Test

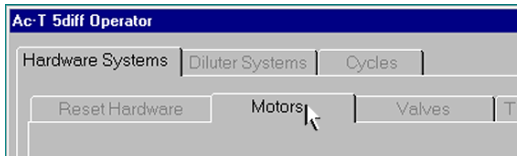
Do this procedure to test the counting syringe motor and reset the counting syringe to its "home" position.

1 **Diagnostics** ▸▸ **Operator**.

2 the **Hardware Systems** tab.

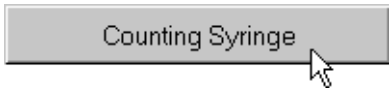


3 the **Motors** tab.



4 **Counting Syringe**.

The instrument exercises the counting syringe motor and returns the counting syringe to its "home" position.

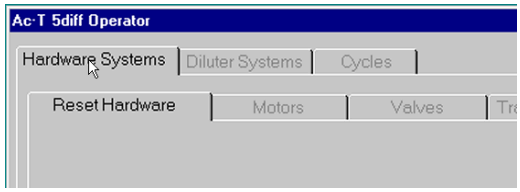


Flow Cell Syringes Test

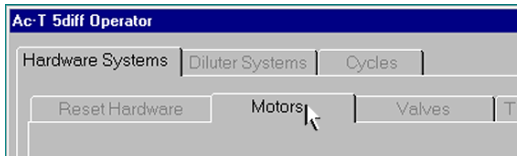
Do this procedure to test the flow cell syringes' motor and reset the flow cell syringes to their "home" position.

1 **Diagnostics** ▸▸ **Operator**.

2 the **Hardware Systems** tab.

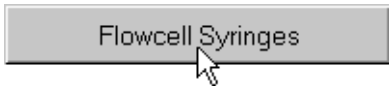


3 the **Motors** tab.



4 **Flowcell Syringes**.

The instrument exercises the flow cell syringes' motor and returns the flow cell syringes to their "home" position.

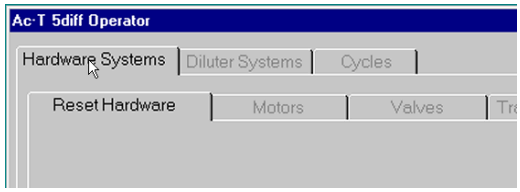


Dilution Syringe Test

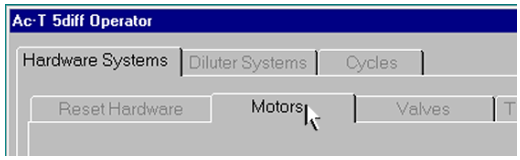
Do this procedure to test the dilution syringe motor and reset the dilution syringe to its "home" position.

1 **Diagnostics** ▸▸ **Operator**.

2 the **Hardware Systems** tab.

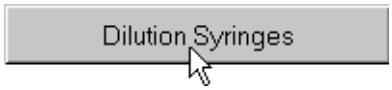


3 the **Motors** tab.



4 **Dilution Syringe**.

The instrument exercises the dilution syringe motor and returns the dilution syringe to its "home" position.

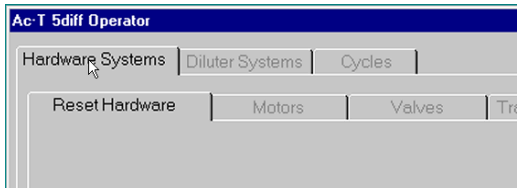


Piercing Mechanism Test

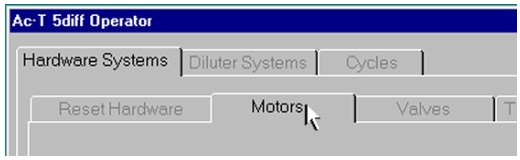
Do this procedure to test the piercing mechanism motor and reset the piercing mechanism to its "home" position.

1 **Diagnostics** ▸▸ **Operator**.

2 the **Hardware Systems** tab.



3 the **Motors** tab.



4 **Piercing Mechanism**.

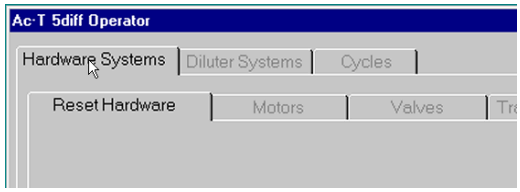
The instrument exercises the piercing mechanism motor and returns the piercing mechanism to its "home" position.

Valves Test

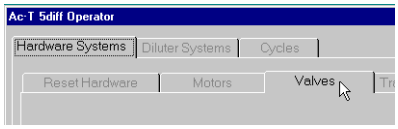
Do this procedure to test the valves' motors and reset the valves to their "home" position.

1 **Diagnostics** ▸▸ **Operator**.

2 the **Hardware Systems** tab.



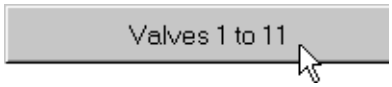
3 the **Valves** tab.



4 the option corresponding to the valves you want to test.

For example, to test the valves 1 through 11, **Valves 1 to 11**.

The instrument exercises the valves' motors and resets the valves to their normal position.

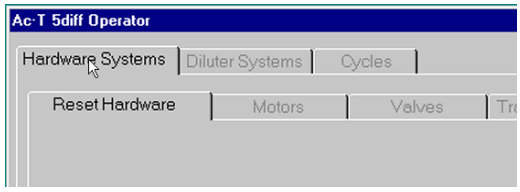


Traverse Service Position

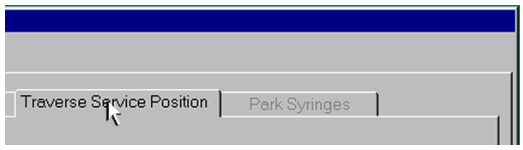
Do this procedure to set the traverse assembly to its "service" position.

1 **Diagnostics** ▸▸ **Operator**.

2 the **Hardware Systems** tab.

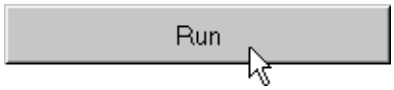


3 the **Traverse Service Position** tab.



4 **OK**.

The traverse assembly is set to the service position.

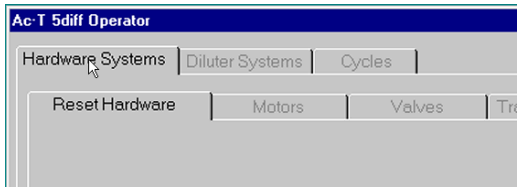


Parking the Syringes

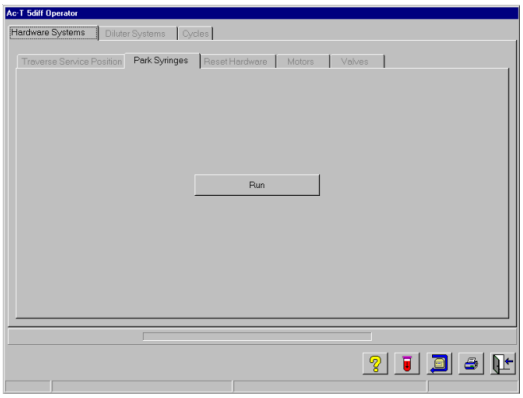
Do this procedure to park the syringes.

1 **Diagnostics** ▸▸ **Operator**.

2 the **Hardware Systems** tab.

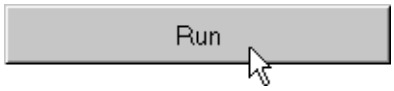


3 the **Park Syringes** tab.



4 **Run**.

The syringes are parked.



11.11 REPLACEMENT PROCEDURES

Changing Reagents

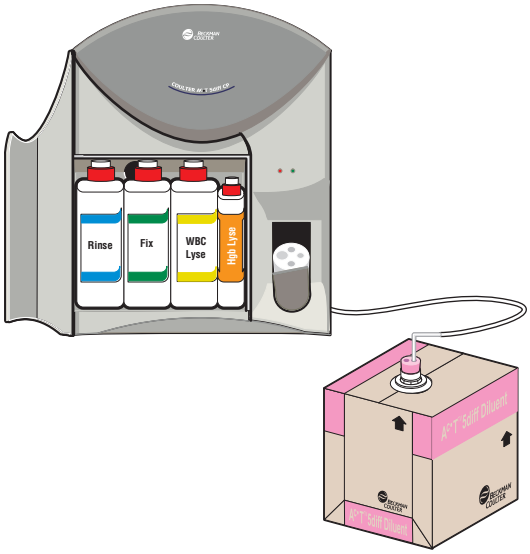
If the instrument determines that there is insufficient reagent to complete the daily workload, *Reagent(s) Low. Insufficient Reagents To Complete Daily Workload* appears after Startup. Specific *reagent low* messages appear for each reagent when applicable. For details about daily workload, see ***Changing the Daily Workload***.

Replace the reagent as instructed in:

- Changing One Reagent: Fix, WBC Lyse, Hgb Lyse, or Rinse Reagents,
- Changing the Diluent Reagent, or
- Changing All Reagents.

Figure 11.7 shows the reagent bottles/containers.

Figure 11.7 Reagent Bottle Location



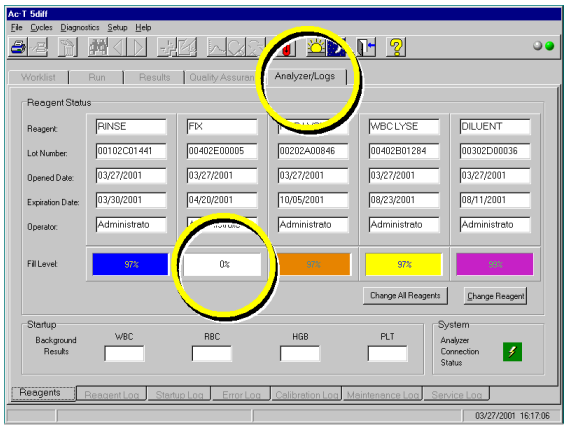
IMPORTANT Risk of instrument error if reagent is poured from one container to another. Never pour reagents from one container to another. Particles at the bottom of the old container can contaminate the new reagent, which will cause unacceptable background results, especially for platelets.

Viewing Reagent Levels

Do this procedure to view a reagent level.

1 the **Analyzer/Logs** tab to display the Reagent window.

Note: If a reagent level indicates 0%, you must replace that reagent. Do ***Changing One Reagent: Fix, WBC Lyse, Hgb Lyse, or Rinse Reagents*** or ***Changing the Diluent Reagent***.



2 Exit this window by selecting another option.

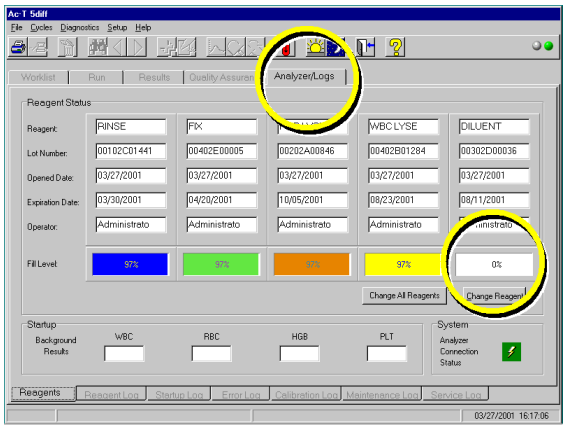
Changing the Diluent Reagent

Do this procedure to replace the Diluent reagent.

To replace either Fix, WBC Lyse, Hgb Lyse, or Rinse reagents, do ***Changing One Reagent: Fix, WBC Lyse, Hgb Lyse, or Rinse Reagents***. To replace all the reagents at the same time, do ***Changing All Reagents***.

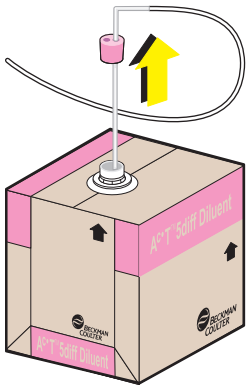
---

1 the **Analyzer/Logs** tab to display the Reagent window.

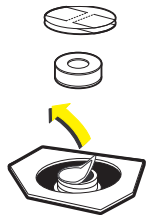


---

2 Remove the stopper assembly from the container.

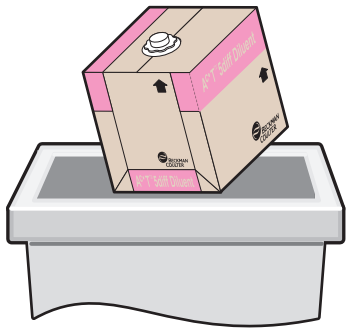


3 Uncap a new diluent container.

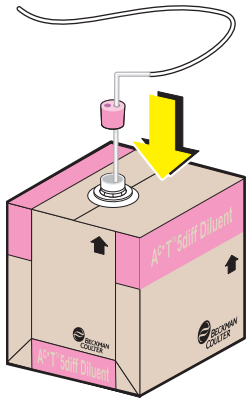


4 Put the cap from the new container onto the empty container.

5 Properly dispose of the empty container.



6 Insert the stopper assembly tube into the new container.

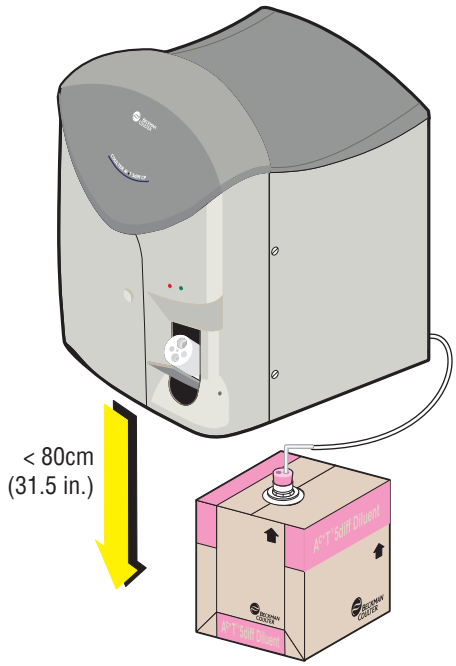


7 Tighten the stopper assembly onto the container to ensure an adequate seal.

IMPORTANT Risk of instrument error if the diluent container is further than 80cm (31.5 in.) below the instrument. Be sure the diluent container is no more than 80cm (31.5 in.) below the instrument.

8 Put the new container no more than 80 cm (31.5 in.) below the instrument.

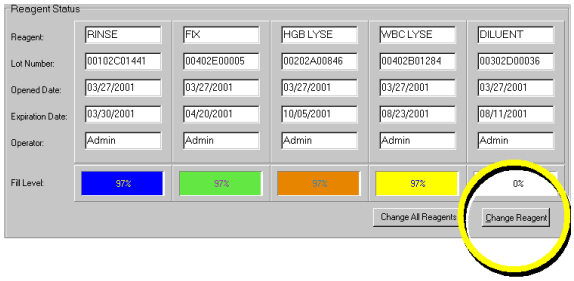
Note: If the system is installed at an altitude of 1,000 meters (3,280 feet) or greater, it is recommended that you place the Diluent 15 cm to 30 cm (6 in. to 12 in.) off the floor.



IMPORTANT Risk of instrument error if the reagent tubing is pinched or twisted. Pinched or twisted tubing prevents a proper flow of the reagent. To ensure that the reagent flows properly through the tubing, ensure that the tubing is not pinched or twisted.

9 Verify that the tubing is not pinched or twisted.

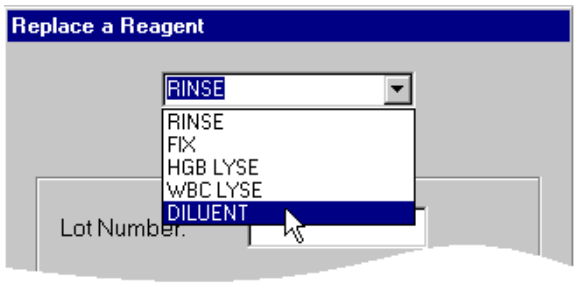
10 **Change Reagent**.



11 Select **DILUENT** from the list:

a. .

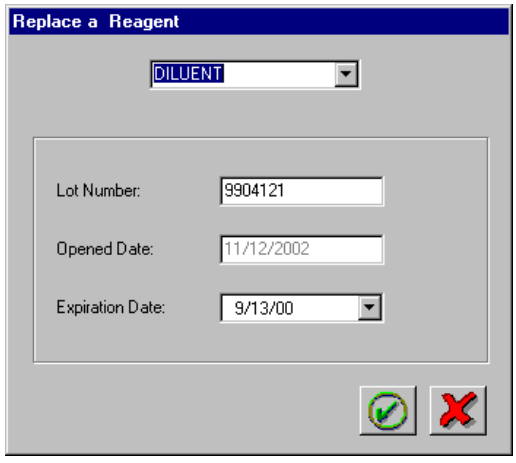
b. **DILUENT**.



12 Enter the lot number from the new reagent container.

If the lot number entered has already been used, the following message appears:

Invalid Reagent Lot Number Entered. Please Enter Correct Reagent Lot Number.

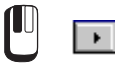


13 Press Tab to move the cursor to the expiration date field.

14 Select the reagent's expiration date:

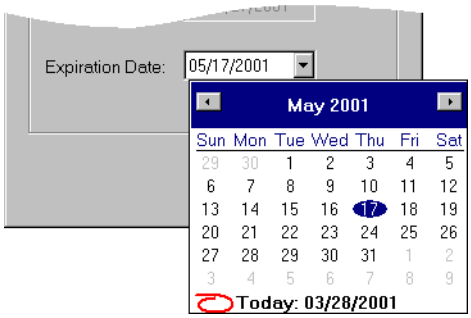
a. at the Expiration Date field to open the calendar that shows the current date.

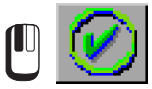
b. Select the expiration date:

1)  as needed to advance to the correct month.

Note: To return to a previous month, .

2) the correct day.



15  to save the reagent's information.

The system updates the reagent information, primes the reagent, and updates the level indicator.

Note: Due to priming, the reagent level may not be displayed as 100%.

ATTENTION: If an instrument error occurs during the reagent replacement procedure, the reagent(s) may not be fully primed.

If an error occurs:

a. Acknowledge and resolve the error.

b. Do ***Heading 11.7, SYSTEM RESET CYCLE.***

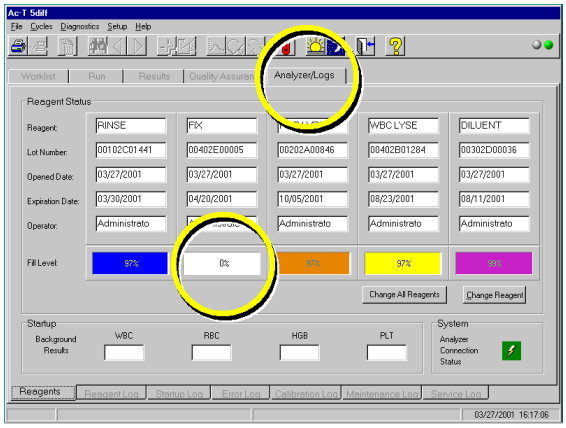
c. Do ***Priming the Reagents*** to manually prime the reagent(s),

Changing One Reagent: Fix, WBC Lyse, Hgb Lyse, or Rinse Reagents

Do this procedure to replace either Fix, WBC Lyse, Hgb Lyse, or Rinse reagents.

To replace only the Diluent, do ***Changing the Diluent Reagent***. To replace all the reagents at the same time. do ***Changing All Reagents***.

1 the **Analyzer/Log** tab.

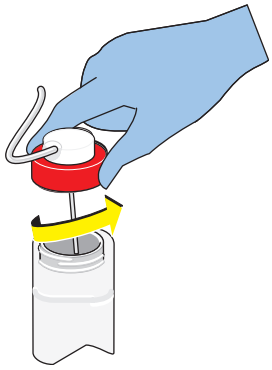


2 Open the reagent compartment door.

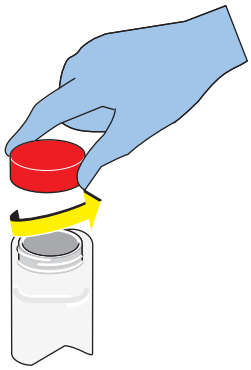
3 Remove the appropriate reagent bottle from the reagent compartment.

(Fix is shown here.)

4 Remove the bottle stopper assembly from the reagent you are replacing.

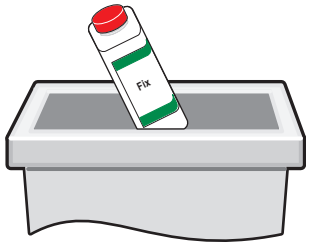


5 Uncap a new reagent bottle.

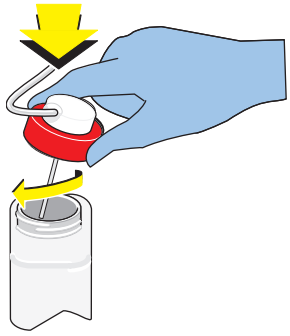


6 Put the cap from the new container onto the empty container.

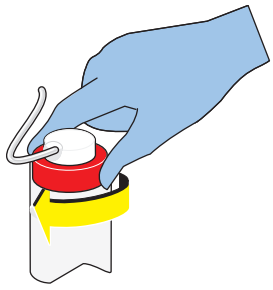
7 Properly dispose of the empty bottle.



8 Insert the stopper assembly tube into the new bottle.



9 Tighten the stopper assembly onto the bottle to ensure an adequate seal.



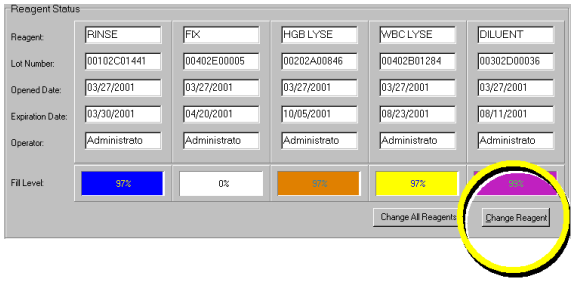
10 Put the new reagent bottle in the reagent compartment.

(Fix is shown here.)

IMPORTANT Risk of instrument error if the reagent tubing is pinched or twisted. Pinched or twisted tubing prevents a proper flow of the reagent. To ensure that the reagent flows properly through the tubing, ensure that the tubing is not pinched or twisted.

11 Verify that the tubing is not pinched or twisted.

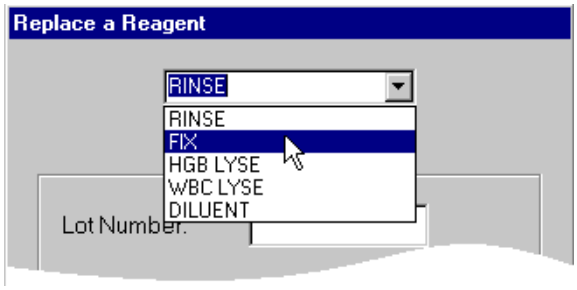
12 **Change Reagent**.



13 Select the reagent to be changed:

a. .

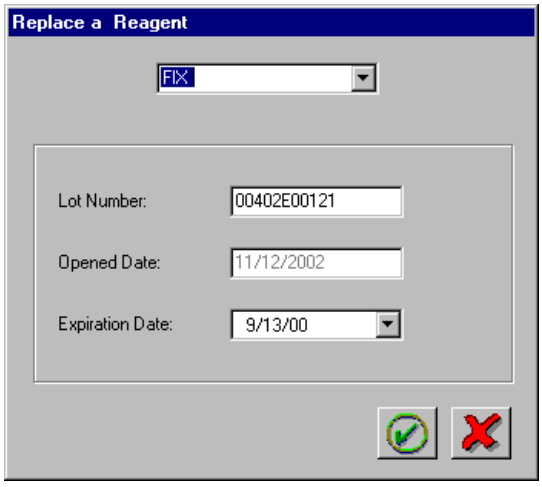
b. Select the reagent.



14 Enter the lot number from the new reagent container.

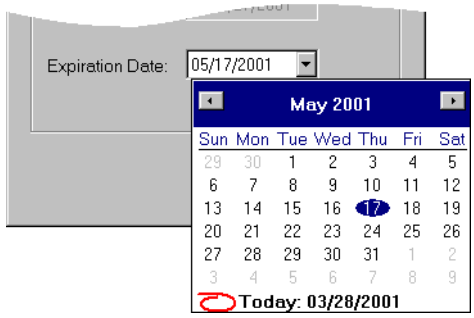
If the lot number entered has already been used, the following message appears:

Invalid Reagent Lot Number Entered. Please Enter Correct Reagent Lot Number.



15 Press Tab to move the cursor to the expiration date field.

16 Select the reagent's expiration date:



a. at the Expiration Date field to open the calendar that shows the current date.

b. Select the expiration date:

1) as needed to advance to the correct month.

Note: To return to a previous month, .

2) the correct day.

17 to save the reagent information.

The system now primes the reagent and updates the level indicator.

Note: Due to priming, the reagent level may not be displayed as 100%.

ATTENTION: If an instrument error occurs during the reagent replacement procedure, the reagent(s) may not be fully primed.

If an error occurs:

a. Acknowledge and resolve the error.

b. Do ***Heading 11.7, SYSTEM RESET CYCLE.***

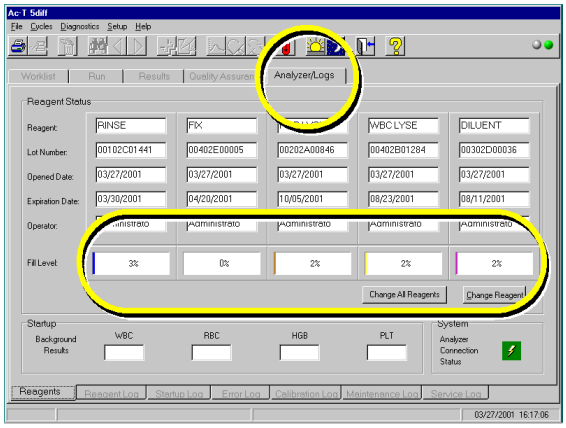
c. Do ***Priming the Reagents*** to manually prime the reagent(s).

18 Close the reagent compartment door.

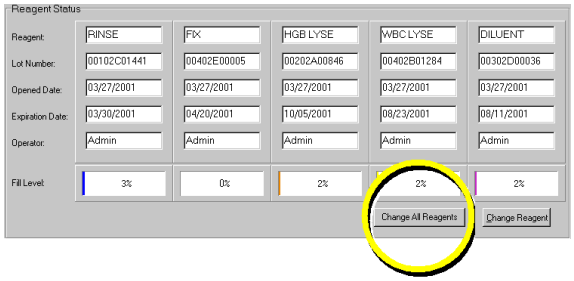
Changing All Reagents

Do this procedure to replace all the reagents at the same time.

1 Click the **Analyzer/Log** tab to display the Reagent window.



2 **Change All Reagents**.

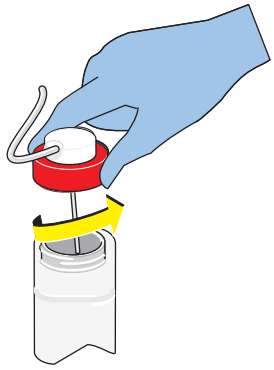


3 Open the reagent compartment door.

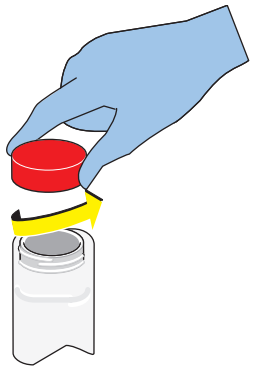
4 Remove the reagent bottles from the reagent compartment.

(Fix is shown here.)

5 Remove the bottle stopper assembly from the reagent you are replacing.

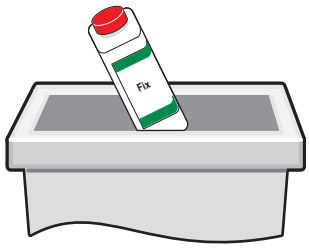


6 Uncap a new reagent bottle.

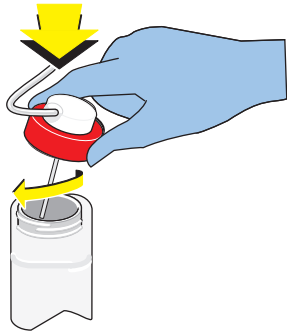


7 Put the cap from the new container onto the empty container.

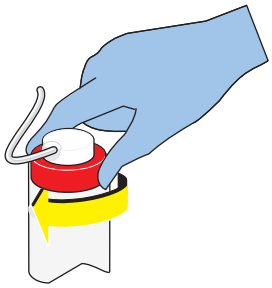
8 Properly dispose of the empty bottle according to your laboratory guidelines.



9 Insert the stopper assembly tube into the new bottle.



10 Tighten the stopper assembly onto the bottle to ensure an adequate seal.



11 Put the new reagent bottle in the reagent compartment.

(Fix is shown here.)

IMPORTANT Risk of instrument error if the reagent tubing is pinched or twisted. Pinched or twisted tubing prevents a proper flow of the reagent. To ensure that the reagent flows properly through the tubing, ensure that the tubing is not pinched or twisted.

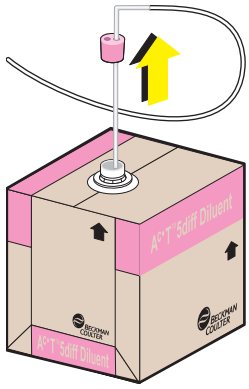
12 Verify that the tubing is not pinched or twisted.

13 Repeat steps 4 through 12 for each reagent.

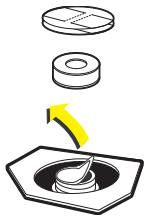
14 Close the reagent compartment door.

15 Replace the Diluent reagent.

16 Unscrew the stopper assembly from the Diluent container.

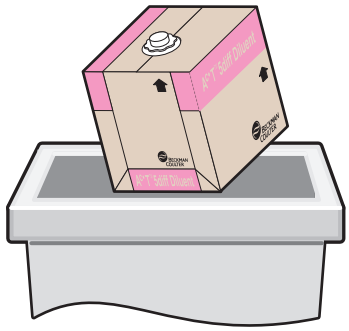


17 Uncap a new Diluent container.

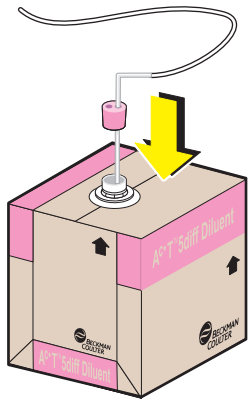


18 Put the cap from the new container onto the empty container.

19 Properly dispose of the empty container.



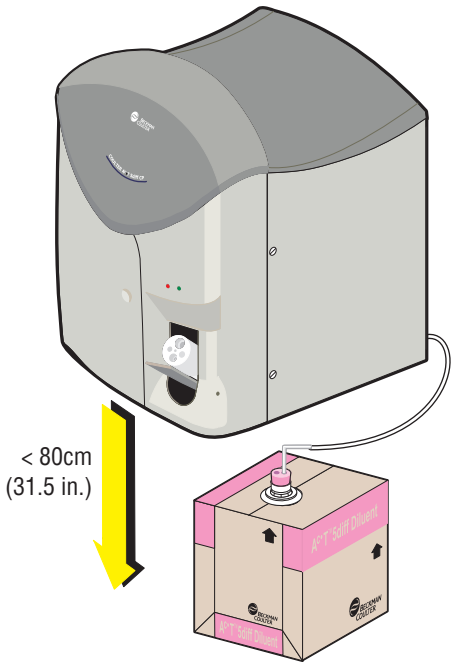
20 Insert the stopper assembly tube into the new container.



21 Tighten the stopper assembly onto the container to ensure an adequate seal.

IMPORTANT Risk of instrument error if the diluent container is further than 80cm (31.5 in.) below the instrument. Be sure the diluent container is no more than 80cm (31.5 in.) below the instrument.

22 Put the new container no more than 80 cm (31.5 in.) below the instrument.

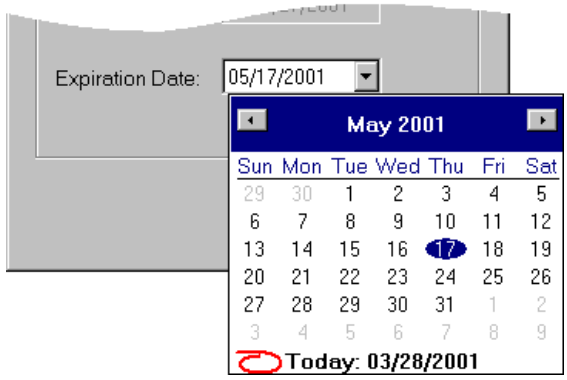


23 Enter the lot number from each new container for every reagent.

If the lot number entered has already been used, the following message appears:

Invalid Reagent Lot Number Entered. Please Enter Correct Reagent Lot Number.

24 Select each reagent's expiration date:



a. at the Expiration Date field to open the calendar that shows the current date.

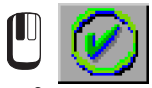
b. Select the expiration date:

1) as needed to advance to the correct month.

Note: To return to a previous month, .

2) the correct day.

3) .

25  to save the reagents' information.

The system updates all of the reagents' information, primes the reagents, and updates the level indicators.

Note: Due to priming, the reagent levels may not be displayed as 100%.

ATTENTION: If an instrument error occurs during the reagent replacement procedure, the reagent(s) may not be fully primed.

If an error occurs:

a. Acknowledge and resolve the error.

b. Do ***Heading 11.7, SYSTEM RESET CYCLE.***

c. Do ***Priming the Reagents*** to manually prime the reagent(s).

Priming the Reagents

The function primes reagents into the instrument.

Do this procedure after service has been performed on the instrument.

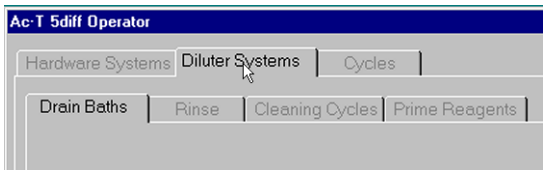
ATTENTION: This function does not reset the reagent cycle. Do not do this procedure when replacing reagents; the system automatically primes each reagent after it has been replaced.

---

1 **Diagnostics** ▸▸ **Operator**.

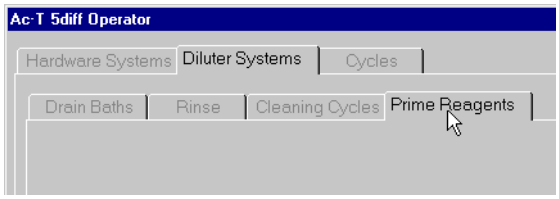
---

2 the **Diluter Systems** tab.



---

3 **Prime Reagents**.



---

4 the desired option.

The instrument primes the selected reagent(s).

Replacing the Waste Container

WARNING Risk of biohazardous condition if the waste sensor alarm battery is not promptly replaced when needed. The waste sensor alarm uses a 9-V alkaline battery for operation. The waste sensor unit will alert you that the battery needs to be replaced. If the waste container is not full and the alarm "chirps" (beeps) at regular intervals, **immediately** replace the old battery with a new 9-V alkaline battery to ensure correct operation of the waste sensor alarm.

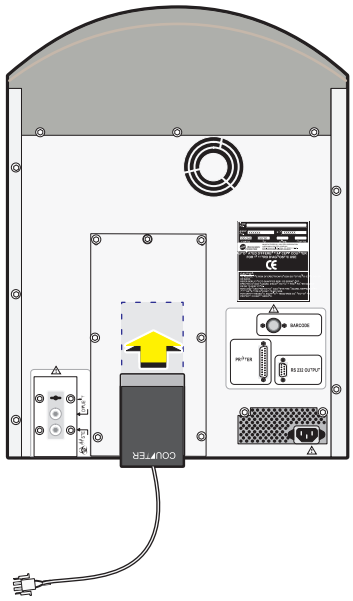
There is a waste sensor alarm unit mounted on back of the instrument (Figure 11.8).

As the waste container fills, there is a float on the sensor that triggers the alarm, which then emits a continuous, intermittent beep until the waste container cap is removed.

If you need to move the waste sensor alarm closer to the waste container, gently pull the alarm unit from the back of the instrument.

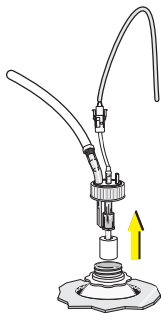
Do this procedure when the waste sensor alarm sounds or as needed.

Figure 11.8 Waste Sensor Alarm Unit Location



1 Turn the Analyzer off.

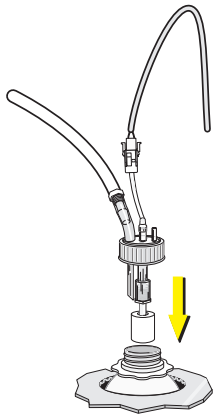
2 Carefully remove the waste container cap (with waste sensor attached).



3 Replace the waste container according to your laboratory's guidelines.

WARNING Risk of personal injury if waste is not neutralized before the waste container is capped. Non-neutralized waste contents may produce gas, which can build up pressure in a capped container. Neutralize waste contents after removing the waste container and before capping it for disposal.

4 Insert the waste sensor float into the new waste container and properly secure the cap.



5 Turn the Analyzer on.

6 Do ***Neutralizing the Waste and Treating for Biohazards***.

Replacing the Flow Cell Lamp

Do this procedure:

- when the flow cell lamp fails, or
- when instructed by a Beckman Coulter representative.

Tools/Supplies needed:

- Hex keys, 2 mm and 3 mm
- Flow Cell lamp

Note: For any part that you use from your spare parts kit, be sure to record the part number for reordering.

---

1 Power down the instrument as instructed in ***Power Down the System*** in Chapter 5.

---

2 Unplug the Analyzer from its power source.

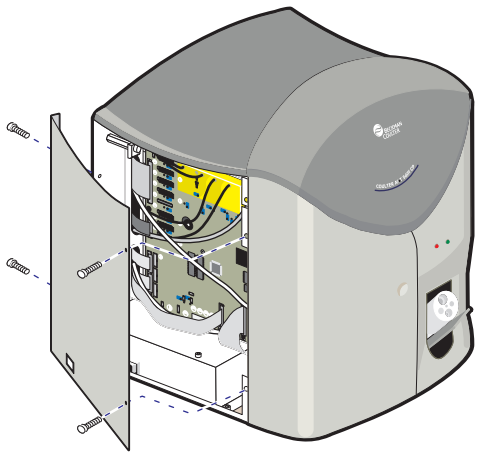
---

3 Remove the left side panel of the instrument:

a. Remove the four hex screws securing the left side panel to the instrument frame.

b. Set the screws aside for use later.

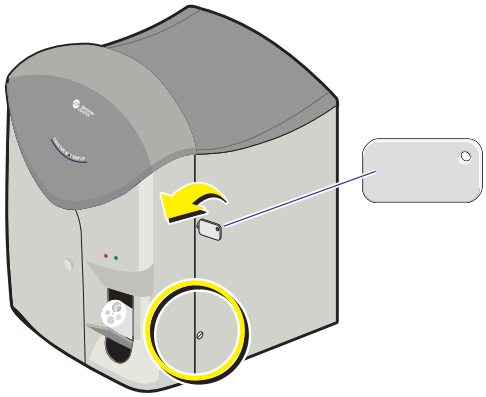
c. Remove the hex screw from the upper front corner inside the left compartment.



4 Open the right side door.

a. Use the door key to loosen the two screws on the right side door.

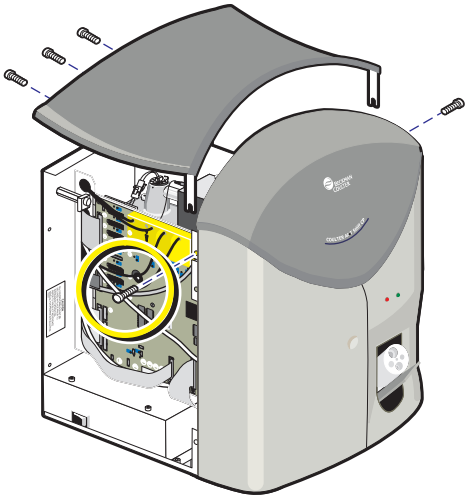
b. Swing open the door.



5 Remove the top cover:

a. Remove the 5 hex screws that secure the top cover to the instrument frame.

b. Carefully remove the top cover and set it aside.



WARNING Risk of personal injury due to hot surfaces within the instrument. Use care when working in this area. Some of the surfaces may be very hot and can burn you. Allow the lamp to cool sufficiently before proceeding.

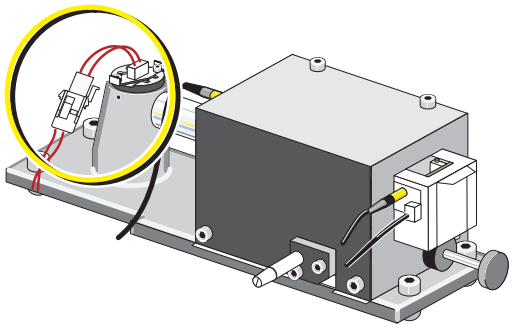
6 Disconnect the lamp from the Power Supply:

a. Locate the lamp and the connector on the left side of the optical bench.

b. Disconnect the lamp from the Power Supply.

c. Note how the existing lamp is seated:

- The metal bracket holding the lamp is keyed to ensure proper positioning.
- There are two different notches: – one is a semi-circle that matches a circular raised area, and the other is a square notch that matches a raised square.



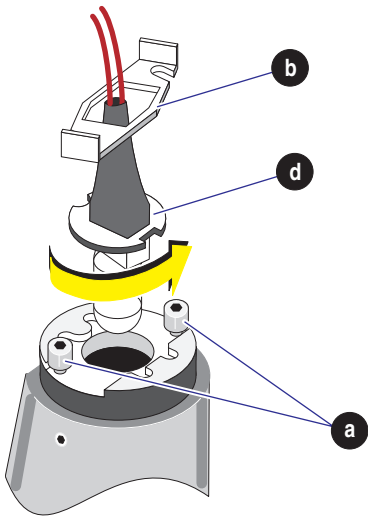
7 Remove the lamp:

a. Use a 2 mm hex key to loosen the two screws a few turns.

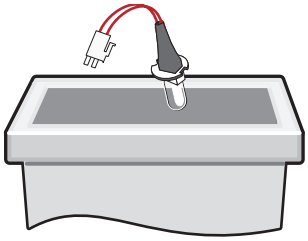
b. Separate the metal bracket from the lamp and cable assembly.

c. Save the metal bracket and screws.

d. Turn the lamp counterclockwise to remove it from its housing.



8 Discard the old lamp assembly.



IMPORTANT Risk of compromising output of the new lamp if the surface is smudged. Fingerprints or other smudges on the lamp can affect output. Do not touch the surface of the lamp.

9 Using care not to touch the surface of the lamp:

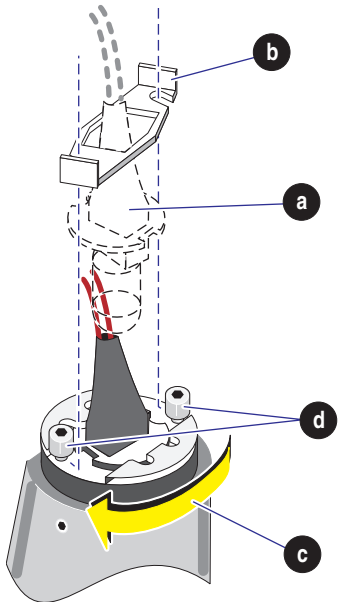
a. Insert the new lamp assembly inside the housing.

b. Place the bracket (with wings up) on the housing.

c. Turn the lamp assembly clockwise until secure.

d. Reinstall the two screws removed in step 7.

e. Reconnect the lamp to the Power Supply.



10 Plug the Analyzer's power cord into its power source (electrical outlet).

11 Power up the system as instructed in ***Power Up the System*** in Chapter 5.

The power on sequence should now perform a startup and background cycle if Auto-Startup is selected.

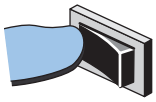
12 Verify correct operation:

a. (if Startup is not automatically done).

b. Verify that the new lamp is lighted.

- If it is, go to step 13.
- If it is not, then troubleshoot the system to determine the problem.

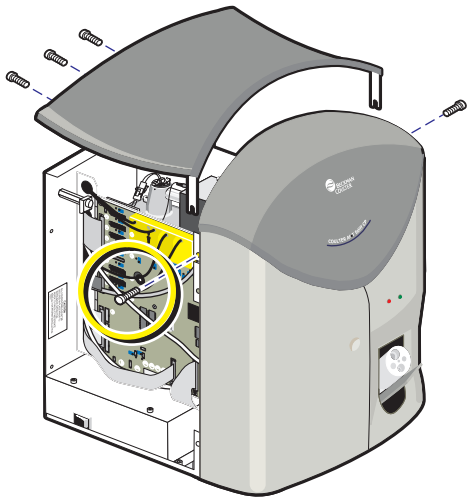
13 When the startup routine is done, turn the instrument off and unplug it from the power outlet.



14 Replace the top cover.

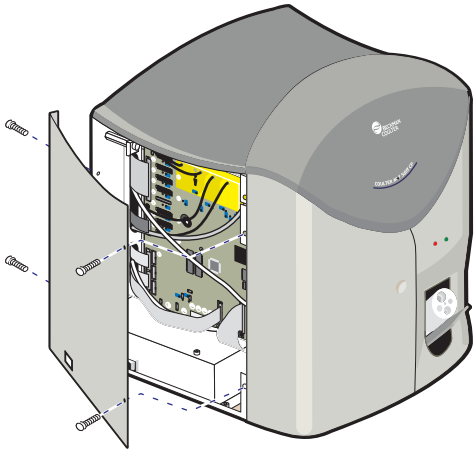
a. Place the top cover on the instrument.

b. Fasten the 5 hex screws to secure the cover to the instrument frame.



c. Re-attach the left side panel, and fasten the four hex screws to secure the door to the instrument frame.

d. Close the right door.



15 After closing all doors and replacing all covers, plug the instrument into the power source.

16 Verify instrument performance by running a fresh, whole-blood sample.

11.12 SYSTEM ERRORS

What Error Messages Mean

Table 11.2 lists errors messages that may appear on the instrument.

Table 11.2 Error Messages

Message	Probable Cause	Suggested Action
"X" Message Windows Have Been Displayed And Have Not Been Closed. No More Message Windows Can Be Displayed.	More than 10 information windows were opened by the system and have not been acknowledged.	Acknowledge all open information windows.
"X" value cannot be less than 1	The value entered is less than 1.	Enter a value of at least 1.
"X" value out of range...	The value entered is out of range.	Enter a value within the range.
A Minimum Of 3 Results Must Be Included To Save The New Cal Factors	At least 3 results are required for calibration calculations and less than 3 have been run.	Run at least three results for calculation results to be generated.
A Minimum of 5 Results Must Be Included to Calibrate	At least 5 calibration runs are required to save calibration factors, and less than 5 are included.	Include at least 5 calibration runs before saving the calibration factors.
A Sample ID is Required Before Sample Will Be Analyzed.	A Sample ID is required to run an analysis.	Enter the sample ID.
A Sample ID Must Be Entered To Save Entry	Attempt was made to create a Worklist entry without a Sample ID.	Enter a Sample ID to create the Worklist entry.
Analyzer Communication Error (Unknown Message)	The Analyzer and Workstation are not communicating.	1. Verify that the cables are properly connected. 2. If the problem persists, contact a Beckman Coulter representative.
Analyzer Must Be Idle Before Attempting To Restore Database.	Attempt was made to restore the database while the system is busy.	Make sure Analyzer is idle before attempting to restore the database.
Bath Enclosure Door Opened	If a cycle is attempted while the right side door is open, this message is generated.	1. Close the door. 2. Do ***Heading 11.7, SYSTEM RESET CYCLE***.
Calibration Failed. Cal Factor Out Of Range.	Attempt was made to save calibration factors, but one or more of the factors are out of range.	Contact a Beckman Coulter representative.

Table 11.2 Error Messages *(Continued)*

Message	Probable Cause	Suggested Action
Cannot Add A Patient Name To Results With A Patient ID.	Attempt was made to add a patient name to a result with an existing Patient ID.	None. A patient name cannot be added to a result with an existing Patient ID.
Cannot Add A Patient Name To Results With An Existing Patient Name.	Attempt was made to add a patient name to a result with an existing patient name.	None. A patient name cannot be added to a result with an existing patient name.
Could Not Connect To Analyzer	Workstation software failed to automatically connect to the Analyzer.	1. Verify proper cable connection between the Analyzer and Workstation. 2. Verify that the Analyzer is on. 3. Verify that you followed the correct Power Up sequence.
Data Not Saved, Value Out Of Range	The results are unacceptable values. They may be out of an expected range or an incorrect data type.	1. Re-enter the data. 2. Re-analyze the sample.
Database Could Not Be Backed Up	Attempt to backup database failed. Attempt was made to backup to a floppy.	1. Retry and save backup to drive D. 2. If the problem persists, contact a Beckman Coulter representative.
Database Restore Unsuccessful!	Attempt to restore a database failed.	1. Retry. 2. If the problem persists, contact a Beckman Coulter representative.
Date Entered Cannot Be Later Than Today's Date	A date later than today's was entered.	Enter a date no later than today's.
Date Entered Cannot Be Prior To Today's Date	A date prior to today's was entered	Enter a date not prior to today's.
Drain Timeout	Problems with draining. Rinse bath filter may be clogged.	1. Do ***Heading 11.7, SYSTEM RESET CYCLE***. 2. If the problem persists, contact a Beckman Coulter representative.
Host Communication Error (>Chars)	There is a problem with the communication or handshaking to the host computer.	Verify that the protocol set up in the host transmission screen matches the protocol expected by the host computer.
Host Communication Error (ACK)	There is a problem with the communication or handshaking to the host computer.	Verify that the protocol set up in the host transmission screen matches the protocol expected by the host computer.
Host Communication Error (ENQ)	There is a problem with the communication or handshaking to the host computer.	Verify that the protocol set up in the host transmission screen matches the protocol expected by the host computer.
Host Communication Error (Internal)	There is a problem with the communication or handshaking to the host computer.	Verify that the protocol set up in the host transmission screen matches the protocol expected by the host computer.

Table 11.2 Error Messages *(Continued)*

Message	Probable Cause	Suggested Action
Host Communication Error (Timeout)	There is a problem with the communication or handshaking to the host computer.	Verify that the protocol set up in the host transmission screen matches the protocol expected by the host computer.
Host Communication Error (Write)	There is a problem with the communication or handshaking to the host computer.	Verify that the protocol set up in the host transmission screen matches the protocol expected by the host computer.
Host Communications Error: Queue Full. Only The First%d Results Will Be Sent.	Attempt was made to transmit more results than the system can spool.	Retransmit results that were not transmitted.
Host Communications Error: Spooler Full. Results Lost.	Attempt was made to transmit more results than the system can spool.	Retransmit results that were not transmitted.
Host Mod. Pat. ID <################ ######> Demo.	If Patient ID is available, the patient demographics in the Worklist were modified by the host.	None.
Host Mod. Sample ID <################ ##> Demo	If Patient ID is not available, the patient demographics in the Worklist were modified by the host.	None.
Incorrect Date Entry	Value entered is not a valid date.	Enter a valid date.
Incorrect Reagent Type Entered. Please Enter Correct Reagent Lot Number.	The reagent lot number for the is invalid for the selected reagent.	1. Verify that the correct reagent is selected for replacement. 2. Re-enter the lot number.
Incorrect Time Entry	Time entered is not a valid time.	Enter a valid time.
Insufficient Disk Space To Backup/Restore Selected Database	Insufficient disk space to backup data to the selected drive.	1. Select a drive (D) with sufficient space to back up the data. 2. If necessary, delete the old database backup, then retry.
Invalid Input!	Invalid data was entered.	Enter valid data.
Invalid Password Entered. Access Denied.	An invalid password was entered.	Enter a valid password.
Invalid Reagent Entered. Please Enter Correct Reagent Lot Number.	An invalid lot number was entered.	1. Verify that the correct reagent is selected for replacement. 2. Re-enter the lot number.
Invalid Reagent Lot Number Entered. Please Enter Correct Reagent Lot Number.	An invalid lot number was entered.	1. Verify that the correct reagent is selected for replacement. 2. Re-enter the lot number.

Table 11.2 Error Messages *(Continued)*

Message	Probable Cause	Suggested Action
No Diluent, Check Level	Diluent reservoir is unable to fill. Diluent reagent is empty.	Check the diluent level. If necessary, do ***Changing the Diluent Reagent***.
No Tube Holder	Tube holder door was closed without a tube holder in place. Tube holder not in 12 o'clock pierce position.	1. Insert the tube holder. 2. Verify that the tube holder is in the pierce position for the desired tube. 3. Close the tube holder door.
XXX Not Reaching Home **Note:** XXX = name of motor.	Motor did not reach home sensor.	1. Do ***Hardware Reset***. 2. Do ***Heading 11.7, SYSTEM RESET CYCLE***. 3. If the problem persists, contact a Beckman Coulter representative.
One or More Selected Calibration Factors Did Not Pass Criteria.	Calibration factors were not within the limits.	Contact a Beckman Coulter representative.
Patient Demographics Received From The Host Cannot Be Modified.	Attempt was made at the Workstation to modify patient demographics received from a host computer.	None. Patient demographics received from a host computer cannot be modified at the Workstation.
Printer Error, Check Paper	An error indication has been sent from the Printer to the instrument; usually a paper out message.	1. Ensure there is paper in the Printer. 2. Refer to the Printer user's manual for additional information.
Reagent(s) Low. Insufficient Reagents To Complete Daily Workload	This message is given at the end of startup if there is not enough reagent remaining to complete the daily workload that has been set up.	Do ***Changing the Diluent Reagent*** and/or ***Changing One Reagent: Fix, WBC Lyse, Hgb Lyse, or Rinse Reagents***.
Reserved Barcode May Not Be Used As Sample ID	Attempt was made to add (create) a Worklist entry with a Sample ID that matches a reserved control.	1. Verify that the Sample ID is correct. 2. Run one analysis into control file.
Result Could Not Be Saved (No Results Available)	Non-numeric (blank) results exist in the control file.	Repeat analysis.
Sam. ID <##################> Analyzing, Can't Mod.	Attempt was made to modify patient demographics while the sample is being analyzed.	None. Once sample analysis begins, the patient demographics cannot be modified from the Worklist.

Table 11.2 Error Messages *(Continued)*

Message	Probable Cause	Suggested Action
Sample ID Already Exists on Pending Worklist. Must Use Edit to Modify An Existing Worklist Entry.	Attempt was made to add (create) a Worklist entry with a Sample ID that already exists in a pending Worklist.	Verify that the Sample ID is correct. • If Sample ID is incorrect, enter the correct Sample ID. • If Sample ID is correct, to modify the existing Worklist entry.
Sample ID Required	Attempt was made to analyze a sample without a Sample ID.	1. Enter the next Sample ID. 2. Analyze the sample.
System Error, Run System Reset Cycle	During a cycle, a system error of the following type has caused the system to stop: • A motor has not returned to its home sensor when expected. • A drain problem has been detected at one of the two drain sensors. • The right side door has been opened during a cycle, losing temperature control at the baths. • A mechanical problem.	1. Do ***Heading 11.7, SYSTEM RESET CYCLE***. 2. If the problem persists, note the error message and contact a Beckman Coulter representative.
Temperature Out Of Range	The temperature in the counting bath compartment is outside of the acceptable range.	1. Ensure the sure right side door is closed. 2. Wait a few minutes. 3. If the problem persists, contact a Beckman Coulter representative.
Timeout Overflow On Rs232	There is a problem with the communication or handshaking to the host computer.	Verify that the protocol set up in the host transmission screen matches the protocol expected by the host computer.
Tube Holder Not Open	Cap Pierce Door sticking, mis-adjusted, obstructed, or defective.	• Check for obstructions or interference with door. • Do the ***OPENING THE TUBE HOLDER DOOR IF JAMMED*** procedure.

11.13 TROUBLESHOOTING GUIDES

Troubleshoot instrument problems by using Table 11.3.

Table 11.3 Troubleshooting Guide

Problem Area	Situation	Probable Cause	Suggested Action
Power	Power will not turn on	Power cord loose or not securely connected.	Ensure that the power cords are properly connected.
		Workstation turned off.	Turn the Workstation on.
		No voltage or wrong voltage at laboratory power outlet.	Ensure the voltage is on and that the outlet is the correct Vac.
		Defective power switch or blown fuse.	Contact a Beckman Coulter representative.
Log on	Software fails to connect to the analyzer during log on		1. Click **Retry**. 2. If the software fails to connect, contact a Beckman Coulter representative.
Startup	Startup failed three times	–	1. Verify the reagents are not expired. Replace reagent if necessary. See ***Changing Reagents***. 2. Do ***Heading 6.1, STARTUP*** again. 3. Do ***Extended Cleaning Procedure***.
	Temperature not reached	Instrument did not reach operating temperature.	Wait 5 minutes to allow the instrument to reach the operating temperature. If the problem persists, contact a Beckman Coulter representative.
	Control verification out of acceptable limits	–	1. Rerun the control. 2. Run a new vial of control. 3. Do ***Extended Cleaning Procedure***. 4. If the problem persists, contact a Beckman Coulter representative.
Sampling	Sampling probe not working properly.	Motor	Contact a Beckman Coulter representative.

Table 11.3 Troubleshooting Guide *(Continued)*

Problem Area	Situation	Probable Cause	Suggested Action
Dilution	Traverse motion	Motor problem	1. Do the appropriate motor test. 2. If the problem persists, contact a Beckman Coulter representative.
	Sample distribution	Pneumatic/syringe problem	Analyze a sample and check that specimen is correctly distributed into the baths. See ***Aspiration***.
	Drain and rinse	Pneumatic/syringe problem	1. Drain the baths. See ***Draining the Baths and/or the Diluent Reservoir***. 2. Rinse the baths. See ***Rinse Baths and Flow Cell***. 3. If the problem persists, contact a Beckman Coulter representative.
Results	Poor reproducibility	Bent sampling probe	Contact a Beckman Coulter representative.
	No parameter results	Bent sampling probe No sample aspiration Reagent problem	Contact a Beckman Coulter representative.
	Excessive flagging	Collection and/or mixing problem with sample Reagent problem	Contact a Beckman Coulter representative.
Printer	Printer does not work	Printer may be turned off.	Turn the printer on.
		Printer may not be setup or connected properly	Refer to the printer user's manual.
Reagents	Level low	Not enough reagent in the bottle/container.	Do ***Changing Reagents***.
	Waste sensor alarm beeps	Waste container is full.	Do ***Replacing the Waste Container***.
		Waste sensor battery is low.	Replace the battery.
Incorrect mechanical operation	Defective stepper motors	Motor alarms are triggered. Current cycle stops.	Do ***Hardware Reset***.
Incorrect pneumatic operation	Leaks or blockages	Reagent alarms are triggered. Current cycle stops.	1. Do ***Heading 11.7, SYSTEM RESET CYCLE***. 2. Do ***Rinse Baths and Flow Cell***. 3. Do ***Priming the Reagents***.

Table 11.3 Troubleshooting Guide *(Continued)*

Problem Area	Situation	Probable Cause	Suggested Action
Incorrect optical operation	Defective optical parts. Dirty optical parts.	Specific flags. Hgb blank cycle measurements are outside acceptable limit.	1. Do ***Heading 11.7, SYSTEM RESET CYCLE***. 2. Do ***Rinse Baths and Flow Cell***. 3. Do ***Priming the Reagents***.
Incorrect electrical operation	Incorrect main supply voltage	Instrument would not initialize.	Ensure correct voltage from power source.

– means not applicable.

11.14 SYSTEM LOGS

The number of entries stored by each log varies:

- The Reagents Log stores up to 50 entries.
- The Startup Log stores up to 50 entries.
- The Error Log stores up to 100 entries.
- The Calibration Log stores up to 50 entries.
- The Maintenance Log stores up to 100 entries.
- The Service Log stores up to 100 entries. (The Service password is required for viewing.)

Prior entries to the log are deleted based on “first in, first out” as the capacity is exceeded. This means that when Reagent Log entry number 51 is ready to be stored, entry number 1 will be deleted to make room for 51. And, when entry number 52 is ready to be stored, entry number 2 will be deleted, and so forth. Therefore, only the most recent entries appear on the log, up to the capacity of the log.

Logs cannot be deleted other than what is described above.

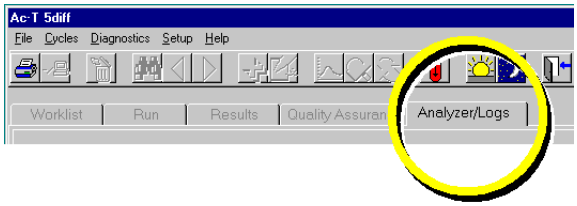
Viewing System Logs

Do this procedure to review one of the following logs:

- Reagents Log.
- Startup Log
- Error Log.
- Calibration Log
- Maintenance Log

---

1 the **Analyzer/Logs** tab.

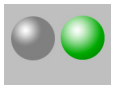


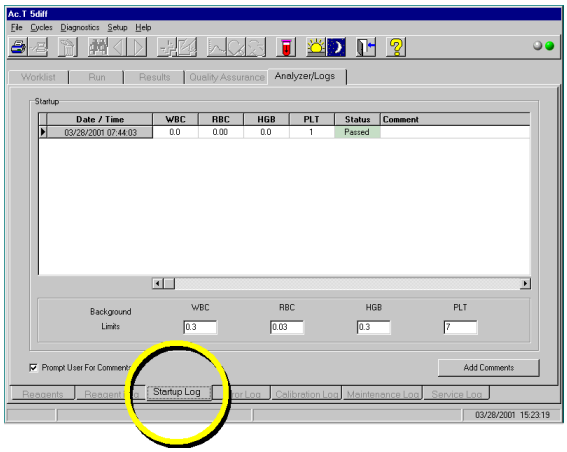
2 the tab for the log you want to view.

For example, to view the Startup Log,

Startup Log.

Note: You can display the Error Log from any screen by double-clicking on either of the System Status indicators at the top right corner of the screen.




Ac.T 5diff
File Cycles Diagnostics Setup Help
Worklist Run Results Quality Assurance Analyzer/Logs
Startup
Date / Time WBC RBC HGB PLT Status Comment
03/28/2001 07:44:03 0.0 0.00 0.0 1 Passed
Background
Limits
WBC RBC HGB PLT
0.3 0.03 0.3 7
Prompt User For Comments
Add Comments
Reagents Reagents Startup Log Error Log Calibration Log Maintenance Log Service Log
03/28/2001 15:23:19

Adding Comments to the Logs

You can enter comments into each of these logs:

- Reagent Log
- Startup Log
- Calibration Log
- Maintenance Log
- Error Log

There are two ways that you can add comments to the logs:

- by ***Adding Comments After Log Entry***, or
- by ***Adding Comments Before Log Entry***.

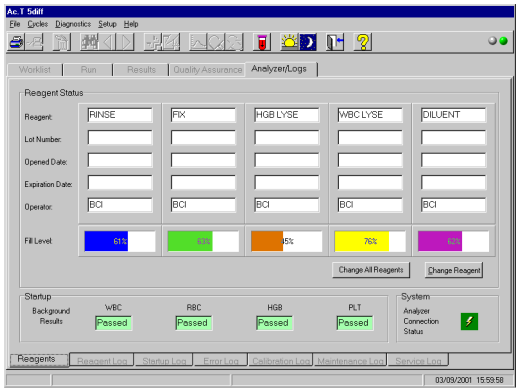
Adding Comments After Log Entry

Do this procedure to add a comment to an existing log entry.

1 the **Analyzer/Logs** tab.

2 the desired log at the bottom of the screen:

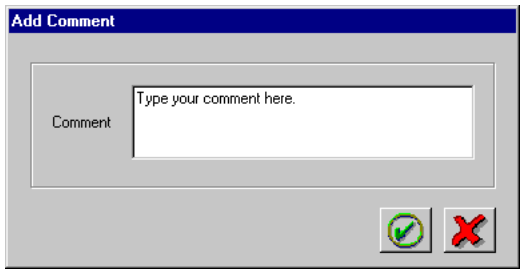
- **Reagent Log**
- **Startup Log**
- **Calibration Log**
- **Maintenance Log**
- **Error Log**



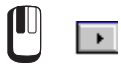
3 Highlight the entry for which you want to add a comment.

4 **Add Comments**.

5 Type your comment.



6 to save.

7 View your comment by scrolling right on the log report by  .

Adding Comments Before Log Entry

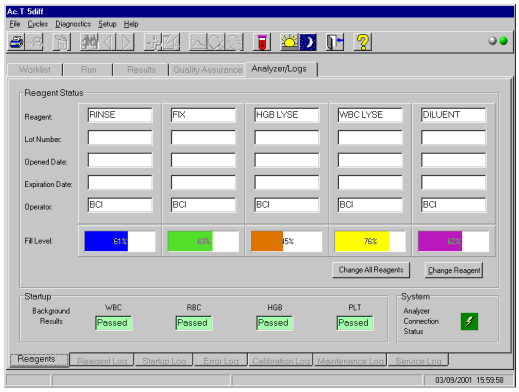
Do this procedure to be prompted for your comments before the log entry is made.

For example, after a Startup is run, the system saves the Startup results to the Startup Log. If you want to be prompted with the Add Comment window before the entry to the log is made, you need to enable the User's Comments prompt for the Startup Log. Otherwise, to add a comment to the Startup Log entry, you would have to do ***Adding Comments After Log Entry***.

1 the **Analyzer/Logs** tab.

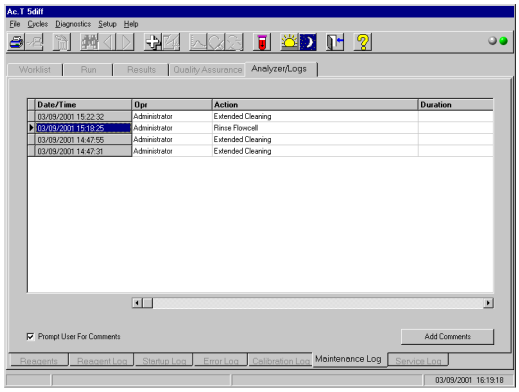
2 the desired log:

- **Reagent Log**
- **Startup Log**
- **Calibration Log**
- **Maintenance Log**
- **Error Log**



3 the box next to **Prompt User for Comments** as need to enable or disable the prompt.

A checkmark in the box means that the option is enabled; otherwise, the option is disabled.



4 to save.

11.15 OPENING THE TUBE HOLDER DOOR IF JAMMED

IMPORTANT Risk of instrument damage if this procedure is done prematurely. Do this procedure only when the system fails to automatically open the tube holder door.

If the system shuts off before the tube holder door opens, do this procedure to manually open the door.

1 .

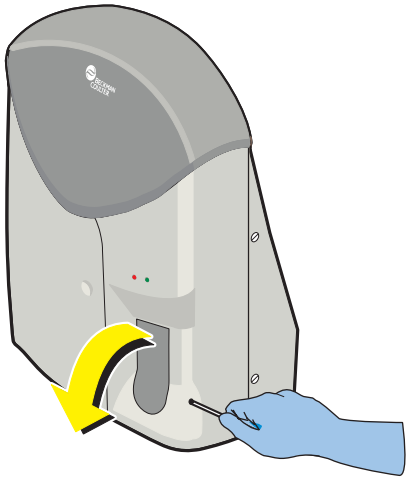
If the tube holder door fails to open, go to step 2.

2 Power down the System as instructed in ***Power Down the System*** in Chapter 5.

3 Unplug the analyzer from its power source (wall outlet).

4 Insert an allen wrench into the hole on the right of the instrument, near the tube holder door, until the door releases.

Note: If the door fails to open or if it becomes jammed again, contact a Beckman Coulter representative.



5 Plug the analyzer into its power source.

6 Power up the system as instructed in ***Power Up the System*** in Chapter 5.

7 Verify system performance and resume normal operation.

A.1 INSTALLATION

A Beckman Coulter representative will install your Analyzer, Workstation, software, and printer.

A.2 DEFAULT CONFIGURATION

Your instrument was configured prior to installation. Table A.1 shows the default configuration information.

Table A.1 Instrument Default Settings

Feature	Default Settings	To Change the Setting
Date format	MM/DD/YYYY	Do ***Changing the Date Format***.
Time format	AM/PM	Do ***Changing the Time***.
Reporting unit	US	Do ***Changing the Reporting Unit***.
Language	ENGLISH	Do ***Selecting a Language***.
Sample ID mode	Manual ID	Do ***Sample ID Autonumbering: Disabling***.
Enable ATL, IMM, PCT, and PDW	NO	Do ***Enabling/Disabling RUO (Research Use Only) Parameters***.
Autoclean frequency	75	Do ***Changing the Auto-Clean Frequency Setting***.
Automatic Startup	Enabled	Do ***Enabling/Disabling Automatic Startup***.
Daily workload	CBC: 10 CBC/DIFF: 40	Do ***Changing the Daily Workload***.

Changes to Instrument Setup

Any time you change the instrument setup, print a setup report for your records. See ***Analyzer and Workstation Configuration Settings*** for details.

A.3 SYSTEM SETUP

Activating Autonumbering and Setting The Starting Number

Before you analyze a sample, a sample ID is required. You can manually enter the sample ID, scan the barcode ID from the sample tube using the optional barcode reader, or have the instrument automatically assign (auto-number) the sample ID.

- If you do not enable the autonumbering feature, you are required to manually type or scan a Sample ID before running the sample.
- If you enable the autonumbering feature, the Sample ID number is automatically incremented by 1 from the previously assigned number each time a sample is analyzed.

Sample ID Autonumbering: Enabling

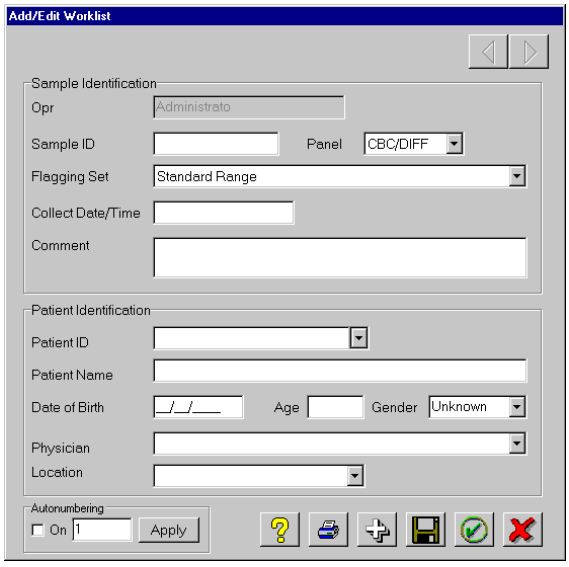
Do this procedure to enable (activate) autonumbering for the Sample IDs.

---

1 the **Worklist** tab.

---

2 .



3 ☑ **Autonumbering ON.**

4 Type the number where you want the autonumbering to begin.

For example, if you want autonumbering to begin at 1, type `1`. The first Sample ID will automatically be number 1.

5 **APPLY**.

6 .

7 Verify that the Sample IDs are correct:

a. the **Run** tab.

b. Confirm that the numbers are correct.

The Sample ID currently being processed appears in the In Progress field in the bottom left of the screen.

The Sample ID to be processed next appears in the Sample ID Next field. For example, if you started autonumbering at 1 and processed that sample, the Next Sample ID will be 2.

Changing the Starting Number for Autonumbered Sample IDs

Do this procedure if you want to change the starting number where autonumbering should begin.

If your laboratory reuses Sample IDs, see ***Heading 2.8, WORKLISTS***, for details about preventing duplicate Sample ID messages.

1 the **Worklist** tab.

2 .

3 Type the starting number.

4 **APPLY**.

5 .

Sample ID Autonumbering: Disabling

Do this procedure to disable (deactivate) autonumbering for the Sample IDs.

1 the **Worklist** tab.

2 .

3 **Autonumbering ON** box until the check mark disappears (☐).

4 **APPLY**.

5 .

Autonumbering is now deactivated, which means that you either have to manually enter the Sample ID or scan Sample ID off the barcode.

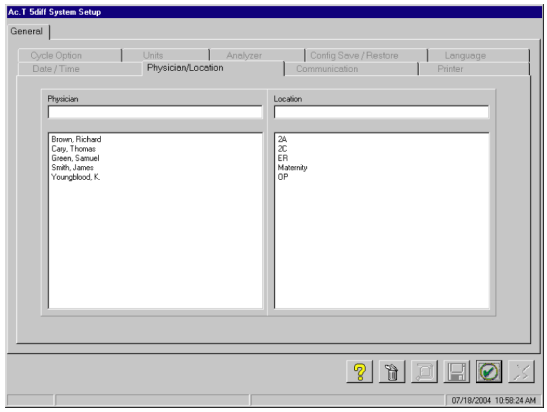
Deleting Physician or Location Names

Do this procedure to delete Physician and Location names. Once deleted, they will no longer appear in the drop-down lists of the Add/Edit Worklist screen but they will remain with stored patient results.

1 **Setup** ▸▸ **System**.

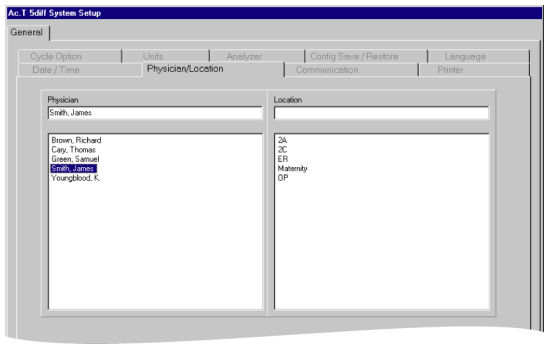
2 Type the password and .

3 the **Physician/Location** tab.



4 Select the name you want to delete. It appears in the field above the list.

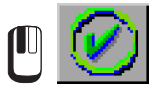
Note: the Physician and Location names appear in alphabetical order.



5 .

6 **OK**.

7 Repeat steps 4 through 6 to delete additional physician or location names.

When finished,  to save and exit the window.

Changing the Reporting Unit

By selecting a reporting unit, you are selecting the format in which numeric results are reported. You can choose from these reporting units:

- US
- SI 1
- SI 2
- SI 3
- SI 4

Table A.2 shows the reporting unit formats for each parameter.

Table A.2 Reporting Unit Format

	Reporting Unit				
Parameter	**US**	**SI 1**	**SI 2**	**SI 3**	**SI 4**
WBC	$10^3/\mu L$	$10^9/L$	$10^9/L$	$10^3/\mu L$	$10^9/L$
RBC	$10^6/\mu L$	$10^{12}/L$	$10^{12}/L$	$10^6/\mu L$	$10^{12}/L$
Plt	$10^3/\mu L$	$10^9/L$	$10^9/L$	$10^3/\mu L$	$10^9/L$
Hct	%	L/L	L/L	L/L	L/L
Hgb	g/dL	g/L	g/L	g/dL	mmol/L
MCV	fL	fL	fL	fL	fL
MCH	pg	pg	pg	pg	fmol
MCHC	g/dL	g/L	g/L	g/dL	mmol/L
RDW	%	%	%	%	%
MPV	fL	fL	fL	fL	fL
Pct	%	%	%	%	%
PDW	%	%	%	%	%
DIFF %	%	%	ratio	%	%
DIFF #	$10^3/\mu L$	$10^9/L$	$10^9/L$	$10^3/\mu L$	$10^9/L$

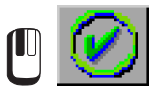
Do this procedure to select a reporting unit format.

ATTENTION: If you change the reporting unit, the system automatically restarts to implement the change.

---

1 **Setup** ▸▸ **System**.

---

2 Type the password and  .

---

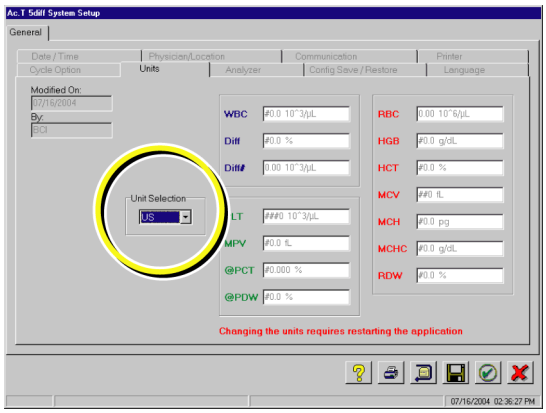
3 **Units** tab.

4 Select the desired reporting unit:

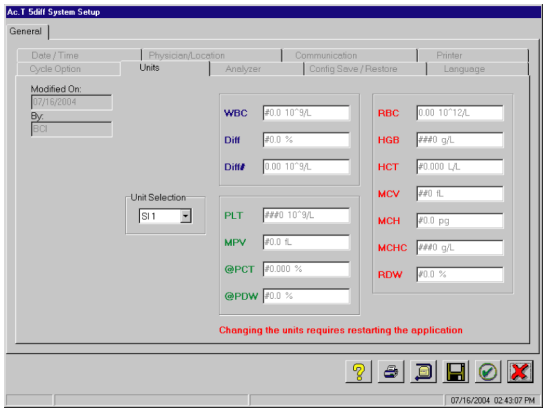
a. at Unit Selection field.

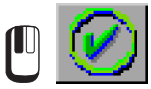
b. Highlight your choice:

- US
- SI 1
- SI 2
- SI 3
- SI 4

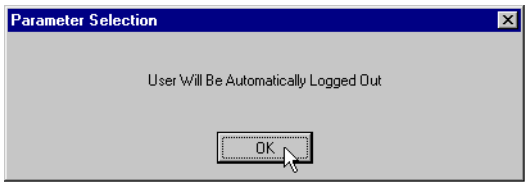


After you select the reporting unit, the screen displays the reporting unit format for each parameter. For example, if you selected SI 3, the SI 3 reporting units are displayed.



5  to save and exit the window.

6 **OK** to confirm that you will be automatically logged out.



7 Wait while the systems logs out.

8 Log in again:

a. When the Begin Logon box appears, simultaneously press Ctrl + Alt + Delete.

b. Type User name `BCI` and press Tab.

c. Type Password `123`.

d. Press Enter or **OK**.

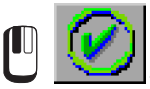
9 Wait for the Analyzer connection to be established.

10 Resume normal operation.

Setting the Date/Time

Changing the Date

1 **Setup** ▸▸ **System**.

2 Type the password and  .

3 the **Date/Time** tab.

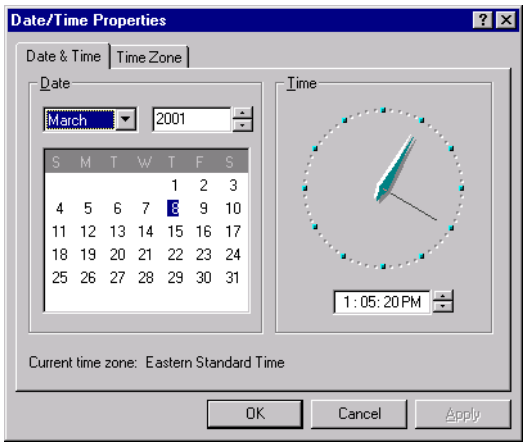
4 **Change Date/Time**.

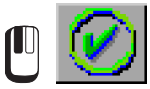
5 Select the current date:

a. Select the month.

b. Select the year.

c. Select the day



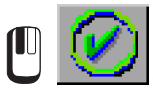
6  to save and exit the window.

OR

APPLY then **OK** to save and remain at this window to change the time. Go to step 5 of ***Changing the Time*** for details.

Changing the Time

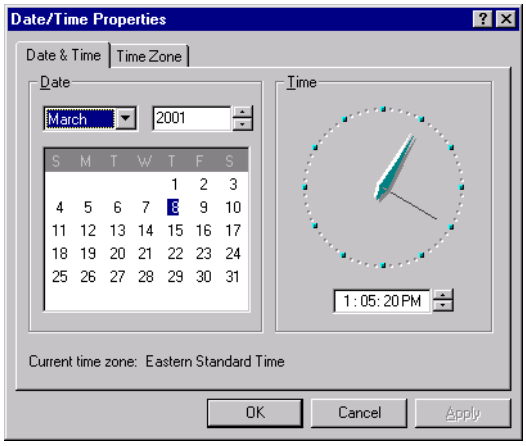
1 **Setup** ▸▸ **System**.

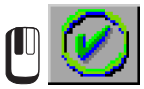
2 Type the password and  .

3 the **Date/Time** tab.

4 **Change Date/Time**.

5 Set the current time by as needed.



6  to save and exit the window.

OR

APPLY then **OK** to save and remain at this window to change the time. Go to step 5 of ***Changing the Date*** for details.

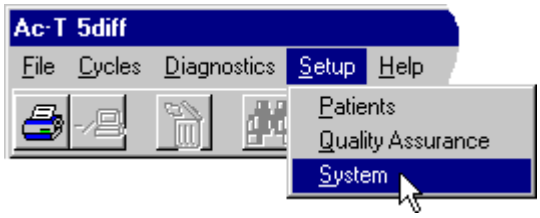
Changing the Time Format

Do this procedure to change the format for how the system time is displayed. The available formats and how each displays time are shown below:

hh:mm:ss ampm (05:30:12 am or pm)
h:mm:ss ampm (5:30:12 am or pm)
H:mm:ss (5:30:12)
HH:mm:ss (05:30:12)

---

1 **Setup** ▸▸ **System**.

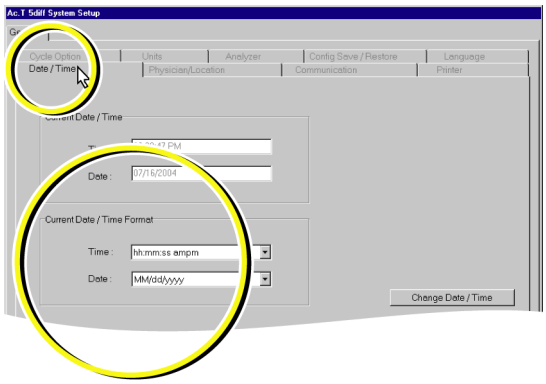


---

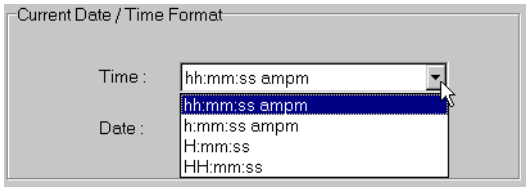
2 Type the password and .

---

3 the **Date/Time** tab.



4 Select the time format:

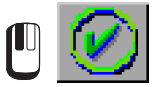


a. at the Time format field.

b. the desired format.

The system updates the format in the Current time field.

5 Save the change:

-  to save and exit from the window.

OR

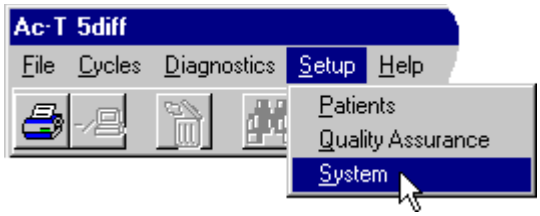
- to save and remain at this window to change the date format. Go to step 4 of ***Changing the Date Format***.

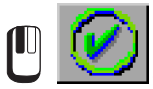
Changing the Date Format

Do this procedure to change the format for how the system date is displayed. The available formats and how each displays the date are shown below.

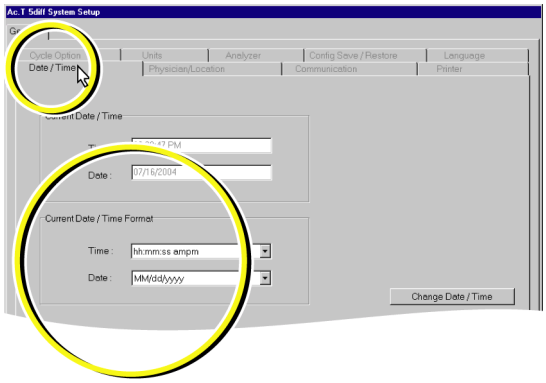
mm/dd/yyyy (03/08/2001)
dd/mm/yyyy (08/03/2001)
yyyy/mm/dd (2001/03/08)

1 **Setup** ▸▸ **System**.



2 Type the password and  .

3 **Date/Time**.

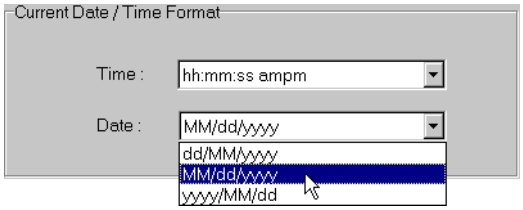


4 Select the date format:

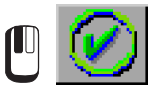
a. at the Date format field.

b. the desired format.

The system updates the format in the Current date field.



5 Save the change:

-  to save and exit from the window.

OR

- to save and remain at this window to change the time format. Go to step 4 of ***Changing the Time Format***.

Changing the Daily Workload

You can specify the daily workload, which is the approximate number of CBC and CBC/DIFF analyses that you expect your laboratory to run each day. The system uses the daily workload settings to perform a reagent capacity check at the end of Startup. The purpose is to determine if there is enough of each reagent to last throughout a workday. Table A.3 shows the default values.

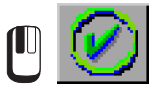
Table A.3 Daily Workload Runs per Panel

Panel	Default	Minimum	Maximum
CBC	10	1	500
CBC/DIFF	40	1	500

If the system determines that there is insufficient reagent to complete the day's work, *Reagent(s) Low. Insufficient Reagents To Complete Daily Workload* appears. You can either determine which reagent is low and change it, or you can continue working until the specific *Reagent Low* message appears, then change the reagent.

Do this procedure to change the daily workload settings.

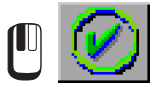
1 **Setup** ▸▸ **System**.

2 Type the password and  .

3 **Cycle Option**.

4 Type the number of daily runs for CBC and/or for CBC/DIFF.

5 Save the changes:

-  to save and exit from the window.

OR

6 to save and remain at this window to continue editing.

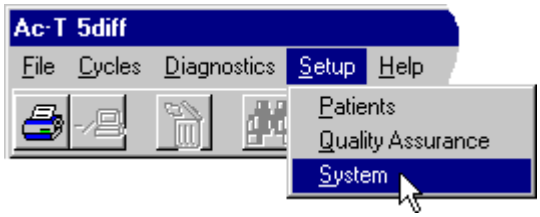
Changing the Auto-Clean Frequency Setting

The instrument automatically performs an autoclean after a specified number of analyses. The default number of analyses is 75. You can change this number to be any number from 1 to 75. For example, if you want the instrument to run the autoclean after 50 analyses, then you would change the number to 50.

Do this procedure to change the auto-clean frequency.

---

1 **Setup** ▸▸ **System**.

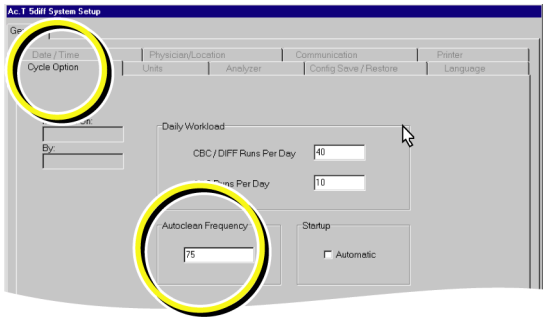


---

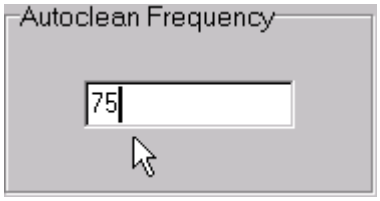
2 Type the password and .

---

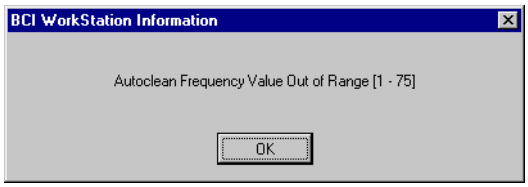
3 the **Cycle Option** tab.



4 Type the number of cycles the system should run before it does an autoclean.



The frequency range is 1 to 75. If you enter a number outside the range, an error message appears. If this happens, **OK** then edit the number to be any whole number from 1 to 75.



5 to save and exit the window.

The autoclean frequency is now set to the number you entered. For example, if you entered 50, then after 50 cycles, the instrument will do an autoclean.

Enabling/Disabling Automatic Startup

If you want your system to do an automatic startup (default) after you log in, do not disable the Automatic Startup feature. **It is recommended that you leave Automatic Startup enabled.**

If you do not want your system to do an automatic startup after you log in, disable the Automatic Startup feature. Keep in mind that if you disable this feature, then you will have to select the Startup option every time you log in.

---

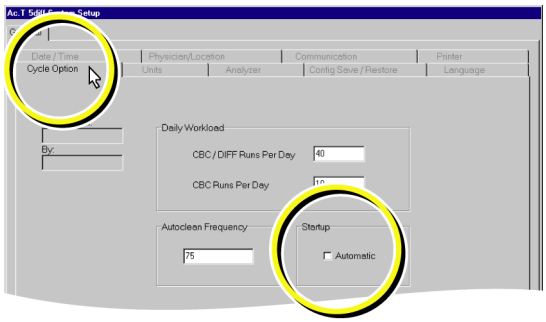
1 **Setup** ▸▸ **System**.

---

2 Type the password and .

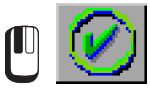
---

3 **Cycle Option** tab.



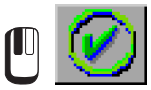
---

4 the box next to **Automatic** to either enable (☑) or disable (☐) the feature.

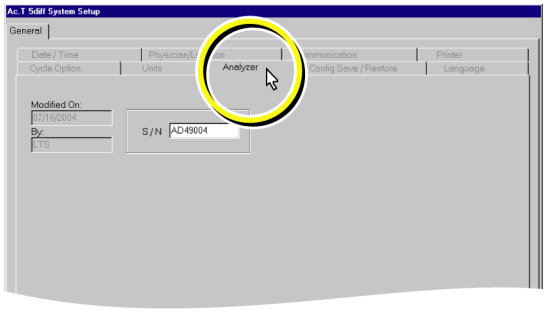
5  to save and exit.

Viewing/Editing the Analyzer's Serial Number (SN)

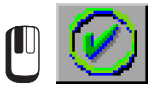
1 **Setup** ▸▸ **System**.

2 Type the password and  .

3 **Analyzer** tab.



4 Edit the serial number, if necessary.

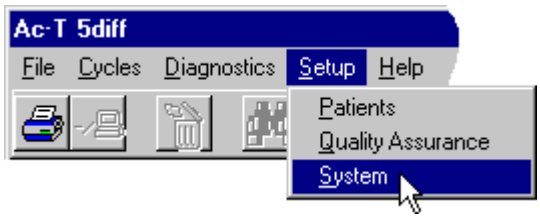
5  to save and exit the window.

Selecting a Language

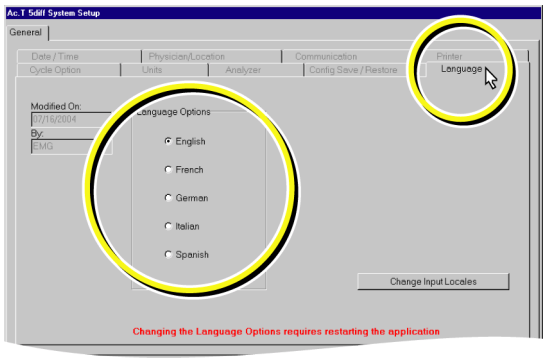
Do this procedure to select the language in which you want the instrument's software to be displayed. Select from:

- English
- French
- Italian
- German
- Spanish

1 **Setup** ▸▸ **System** ▸▸ **General**.



2 the **Language** tab.



3 the desired language.

Note: If you want to edit input locales, such as language-specific keyboards, contact a Beckman Coulter representative.

4 **Change Input Locales** and confirm settings.

5 to save and exit the window.

Note: A message displays to remind you that changing the Language Options requires restarting the application.

Configuring the Printer

Defining Printer Properties

Printer properties include paper size, paper orientation (portrait or landscape), paper source, print quality, and so forth.

Do this procedure if you want to change any of the printer properties. Actual printer setup information may vary depending on the printer used.

---

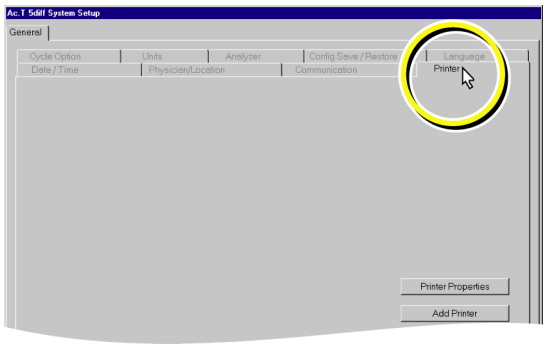
1 **Setup** ▸▸ **System**.

---

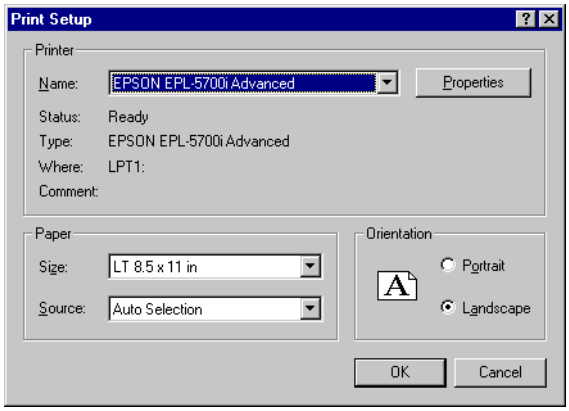
2 Type the password and .

---

3 **Printer** tab.



4 **Printer Properties**.



5 Select the printer from the Name list:

a. at the Name field.

b. Highlight the desired printer.

c. Note: If the printer you want does not appear in the list, you can add the printer. See ***Adding a Printer*** for details.

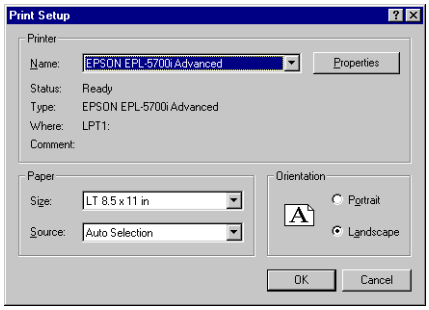
ATTENTION: Use printers available in this field only. These printers and their drivers have been validated for use with the AC•T 5diff CP system.

6 Select the desired printer settings.

7 For additional property settings,

Properties.

Page setup options such as paper size, paper source, paper orientation, copy count, and other options are shown.



8 **OK** to close the advanced properties screen.

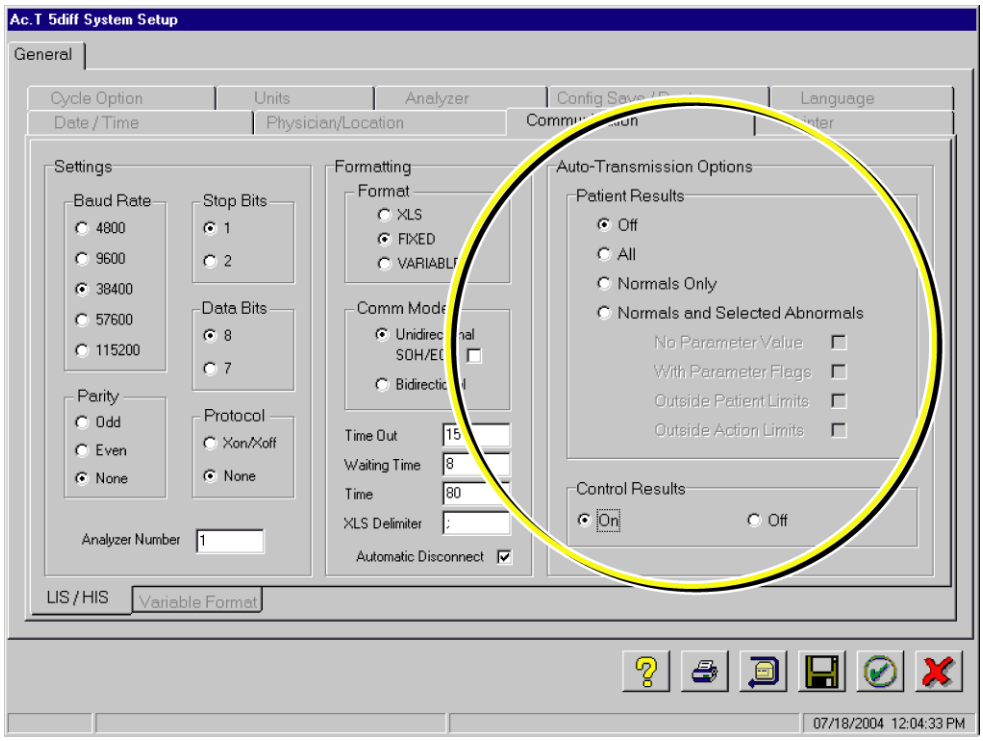
9 **OK** to close the print setup screen.

10 to save and exit the window.

Adding a Printer

ATTENTION: If you want to add a Windows NT-compatible printer to your system, contact a Beckman Coulter representative.

Defining Results Autotransmission Settings



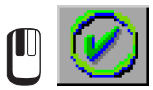
Autotransmission of the results to the host computer occurs based on the settings defined in the Auto-Transmission Option of system setup. You can autotransmit patient and/or control results. Refer to the Host Transmission Specification manual for details on configuring the host communication protocol.

Do this procedure to define the auto-transmission settings for transmitting results to a host computer, if applicable.

---

1 **Setup** ▸▸ **System**.

---

2 Type the password and  .

3 the **Communication** tab.

4 At Patient Results, select one of the following options:

- **Off (turns** off autotransmission)
- **All** (autotransmits all patient results to the host computer)
- **Normals Only** (autotransmits normal patient results only)
- **Normals and Selected Abnormals** (autotransmits all normal patient results and the abnormal results that you define)
  - No Parameter Value
  - With Parameter Flags
  - Outside Patient Limits
  - Outside Action Limits

5 At Control Results, select **On** if you want to autotransmit control results to the host. (Only available for software version 2.00 and above).

6 to save and exit the window.

Analyzer and Workstation Configuration Settings

In addition to restoring Analyzer and Workstation configuration settings from a saved copy, you can save and print current Analyzer and Workstation settings.

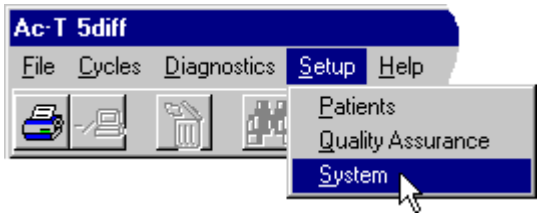
Saving Analyzer Configuration Settings

This procedure allows you to save the Analyzer's current configuration settings to the Workstation's hard drive or to a floppy disk. You can restore saved settings, if necessary. The Beckman Coulter representative performs this procedure at installation.

Do this procedure if you change the Analyzer's configuration.

---

1 **Setup** ▸▸ **System**.

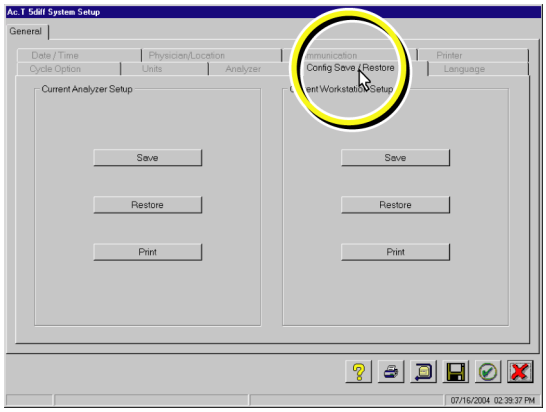


---

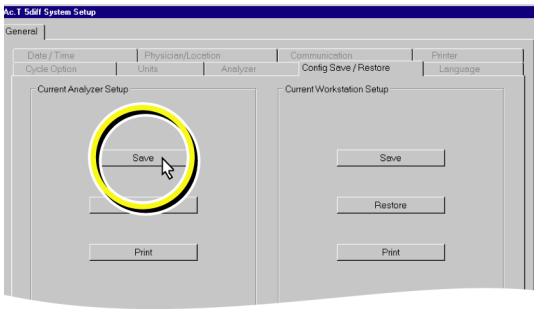
2 Type the password and .

---

3 **Config. Save/Restore** tab.



4 **Save** in **Current Analyzer Setup** area.



5 Indicate where the settings should be saved.

- If you want the settings to be saved to the hard drive,

  Hard Drive then .
  Beckman Coulter recommends that you save the information to your hard drive.
- If you want the settings to be saved to a floppy disk:

  1) Insert the disk into drive A.

  2) **Floppy Disk**.

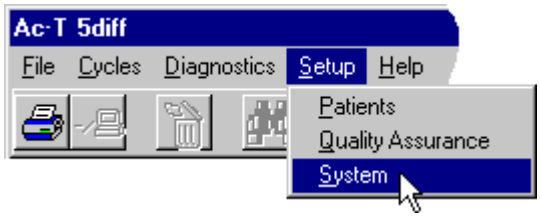
  3) .

Restoring Analyzer Configuration Settings

Do this procedure if you want to restore previously saved Analyzer settings to be the current settings.

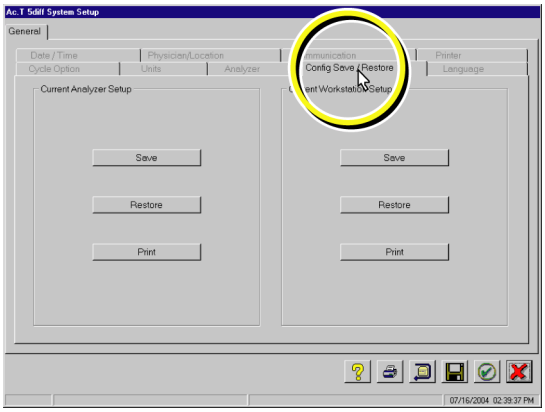
IMPORTANT Workstation Configuration restore is not recommended if the database contains patient results. After a restore, the range values in the Workstation Flagging Sets are replaced by the range values from the restored Flagging Sets. Existing Patient samples will remain flagged with the range values as analyzed. However, the Flagging Set ranges reported are changed to the values from the restored Flagging Sets. Verify Flagging Set range values after restore and prior to reporting patient results.

1 **Setup** ▸▸ **System**.

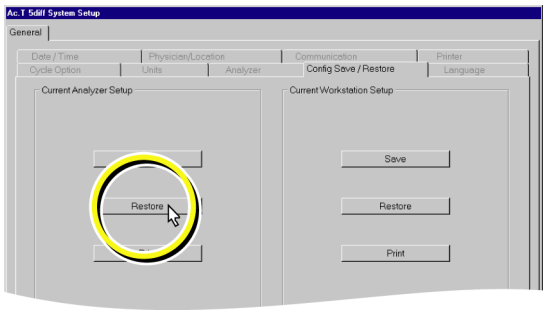


2 Type the password and .

3 **Config. Save/Restore** tab.



4 **Restore** in **Current Analyzer Setup** area.



5 Indicate from where the settings should be restored.

- If you want the settings to be restored from the hard drive,

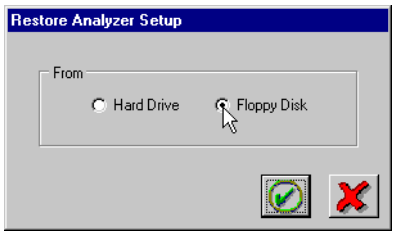
  Hard Drive then .

- If you want the settings to be restored from a floppy disk:

  1) Insert the disk into drive A.

  2) **Floppy Disk**.

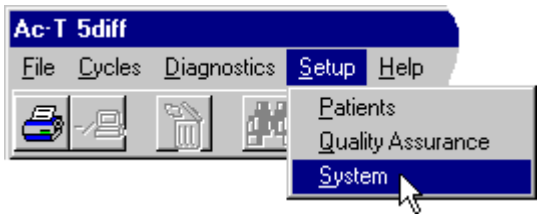
  3) .

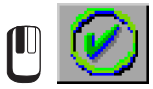


Printing Analyzer Configuration Settings

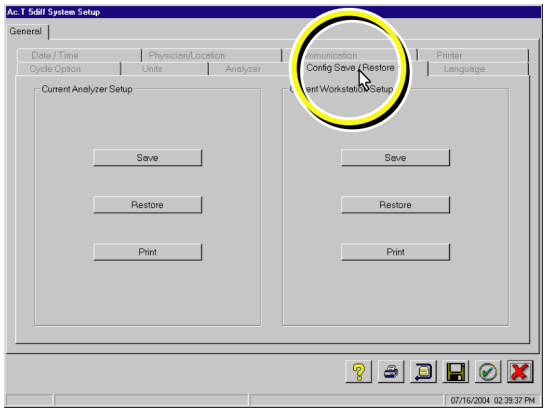
Do this procedure to print the current Analyzer configuration settings.

1 **Setup** ▸▸ **System**.



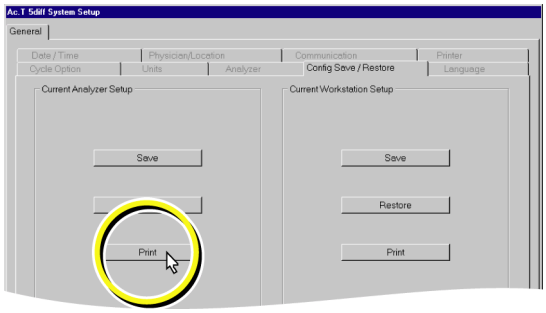
2 Type the password and  .

3 **Config. Save/Restore** tab.



4 **Print** in **Current Analyzer Setup** area.

A detailed report on the Analyzer's settings is printed.



5 Keep the printout for your records. At installation, the Beckman Coulter representative gave you a copy of the printout based on the settings at the time of installation.

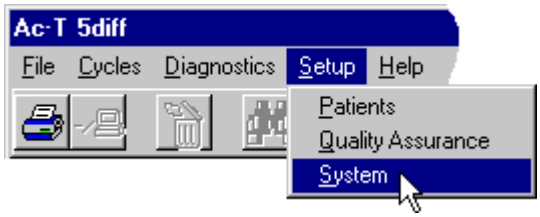
Saving Workstation Configuration Settings

This procedure allows you to save the Workstation's current configuration settings to the Workstation's hard drive or to a floppy disk. You can restore saved settings, if necessary.

Do this procedure if you change the Workstation's configuration.

---

1 **Setup** ▸▸ **System**.

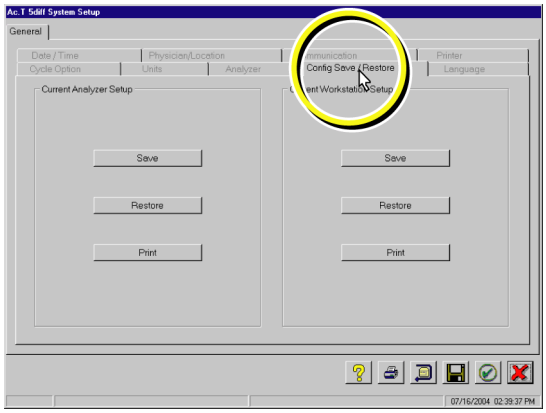


---

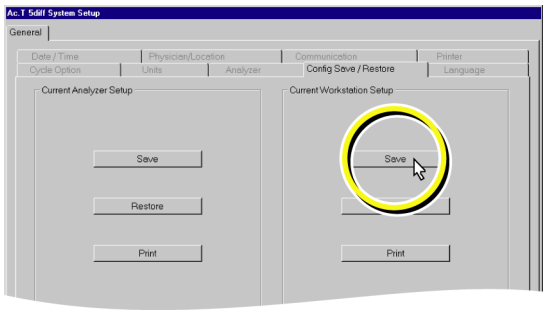
2 Type the password and .

---

3 **Config. Save/Restore** tab.



4 **Save** in **Current Workstation Setup** area.



5 Indicate where the settings should be saved.

- If you want the settings to be saved to the hard drive,

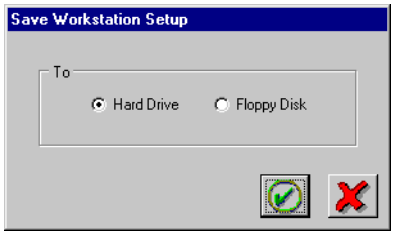
  Hard Drive then .

- If you want the settings to be saved to a floppy disk:

  1) Insert the disk into drive A.

  2) **Floppy Disk**.

  3) .

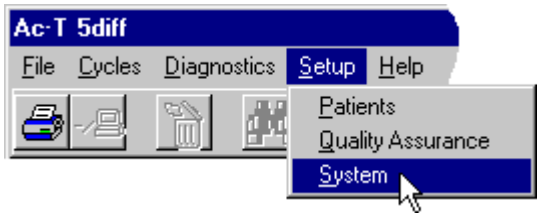


Restoring Workstation Configuration Settings

Do this procedure if you want to restore previously saved Workstation settings to be the current settings.

---

1 **Setup** ▸▸ **System**.

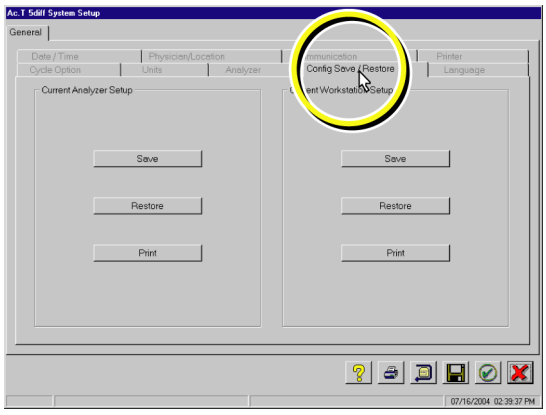


---

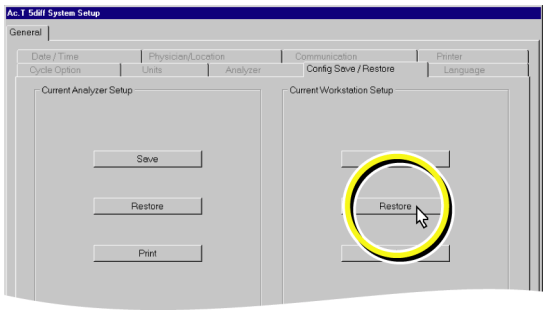
2 Type the password and .

---

3 **Config. Save/Restore** tab.



4 **Restore** in **Current Workstation Setup**.



5 Indicate from where the settings should be restored.

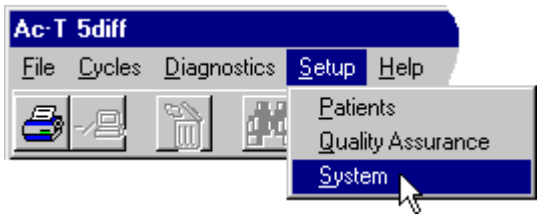
- If you want to restore the settings from the hard drive, **Hard Drive** then .
- If you want the settings to be restored from a floppy disk:
  1) Insert the disk into drive A.
  2) **Floppy Disk**.
  3) .

Printing Workstation Configuration Settings

Do this procedure to print the current Analyzer configuration settings.

---

1 **Setup** ▸▸ **System**.

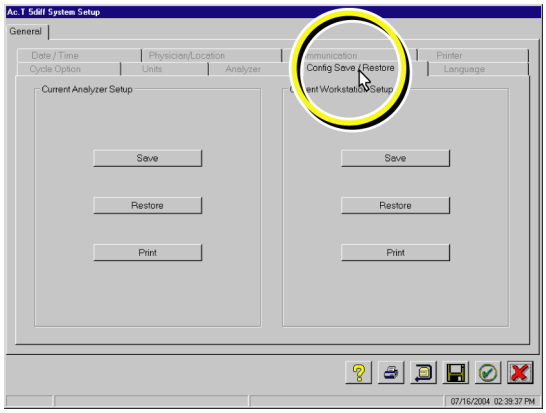


---

2 Type the password and .

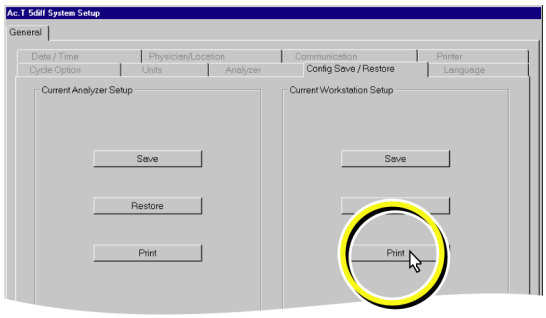
---

3 **Config. Save/Restore** tab.



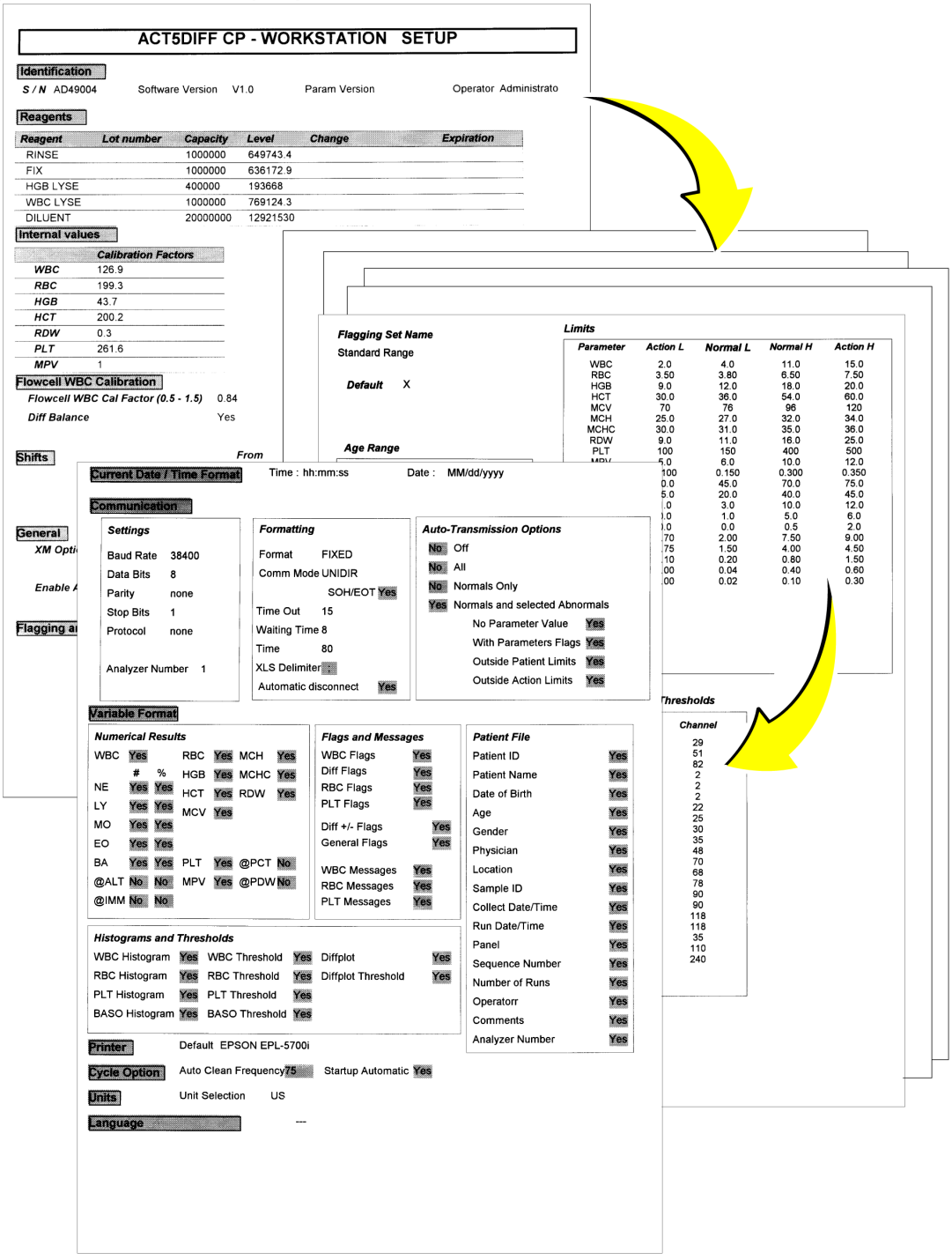
4 **Print** in **Current Workstation Setup**.

A detailed report on the Workstation's settings is printed (Figure A.1).



5 Keep the printout for your records.

Figure A.1 Workstation Setup Report



Defining the Host Communication Settings

Changing the LIS/HIS communication settings affects what information is sent to and received from a host computer. Typically, this information is already set up in your system by a qualified technician using the information in the Host Transmission Specification document. Consult a Beckman Coulter representative before editing the host communication settings.

A.4 PATIENT SETUP

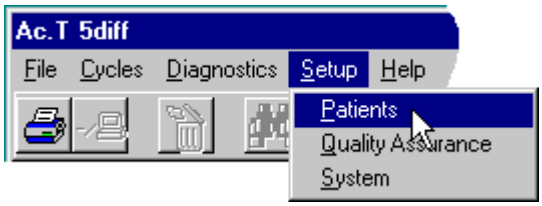
Working With Flagging Sets (Ranges)

Note: Flagging set modification (name or limits) will not be allowed if there are any previously analyzed sample result(s) with this flagging set in the database.

Selecting a Default Flagging Set

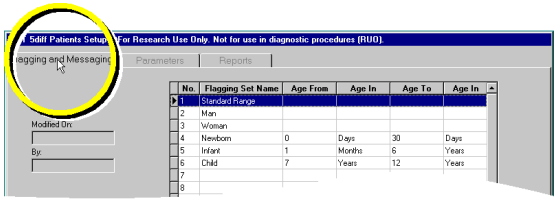
Do this procedure to select a default flagging set.

1 **Setup** ▸▸ **Patients**.

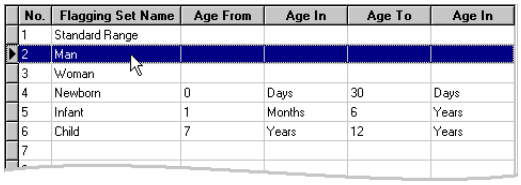


2 Type the password and .

3 the **Flagging and Messaging** tab.



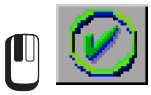
4 Highlight the flagging set that you want to be the default.



No.	Flagging Set Name	Age From	Age In	Age To	Age In
1	Standard Range				
2	Man				
3	Woman				
4	Newborn	0	Days	30	Days
5	Infant	1	Months	6	Years
6	Child	7	Years	12	Years
7					

5 **Set As Default**.

6 Save the change:

-  to save and exit from the window.

OR

- to save and remain at this window.

The flagging set name that you selected is now defined as the default flagging set.

Editing Patient Limit Ranges in a Flagging Set

Do this procedure to edit patient limit ranges within a flagging set.

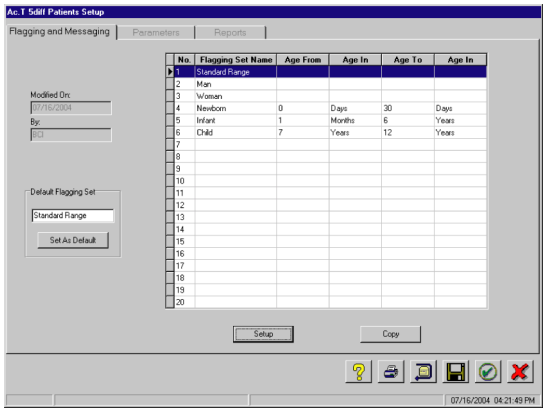
ATTENTION: The 'Standard' flagging set cannot be edited. The age range cannot be edited on any flagging set.

1 **Setup** ▸▸ **Patients**.

2 Type the password and .

3 the ***Flagging and Messaging*** tab.

4 Highlight the flagging set that you want to edit.



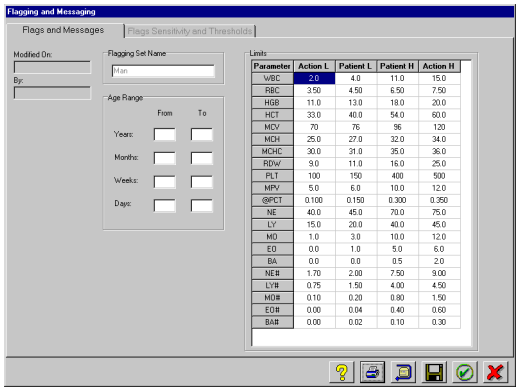
5 **Setup**.

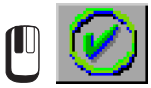
6 Edit the patient limit ranges:

a. Highlight the number to be changed.

b. Type the new number.

c. Press Tab to move between the fields.



7  to save and exit the window.

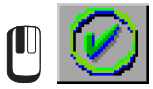
Creating Additional Flagging Sets

You can create up to 14 additional flagging sets, for a total of 20 flagging sets for your system. (Six are already pre-defined and installed.)

Do this procedure to create a new flagging set.

1 Verify that the flagging set you want to "Copy To" is created. See ***Creating Additional Flagging Sets*** for details.

2 **Setup** ▸▸ **Patients**.

3 Type the password and  .

4 the **Flagging and Messaging** tab.

5 Select an empty (available) flagging set or select the next available (empty) row.

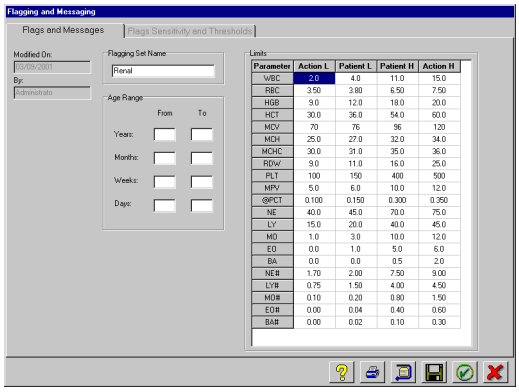
For example, if there are only the 6 pre-defined flagging sets on your system, row 7 is the next available row.

6 **Setup**.

7 Type the flagging set name.

For example, if you want to create a flagging set for renal patients, you may want to name the flagging set `Renal`.

Note: Do not use an apostrophe or any other punctuation in the flagging set name.



ATTENTION: The action and patient limits applied to a new flagging set are those from the Standard Range flagging set. Remember that the age range cannot be edited.

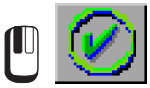
8 Edit the limits' ranges, if necessary:

a. Highlight the number to be changed. **Note**: You cannot enter age ranges for the flagging sets.

b. Type the new number.

c. Press Tab to move between the fields.

For an alternative method, see ***Copying Action Limits and Patient Limits to Another Flagging Set***.

9  to save and exit the window.

The new flagging set is created and now appears in the list of defined flagging sets.

Flag Sensitivity and Thresholds

The options under the **Flag Sensitivity and Thresholds** tab are **for Service use only**.

IMPORTANT Do not make any adjustments without first consulting a Beckman Coulter representative. Otherwise, your system may not perform to specifications. Any change to thresholds or sensitivity affect overall system performance.

Copying Action Limits and Patient Limits to Another Flagging Set

Do this procedure to copy action limits and patient limits from one flagging set to another existing flagging set. A flagging set must already be created before you can copy to it.

1 **Setup** ▸▸ **Patients**.

2 Type the password and .

3 the **Flagging and Messaging** tab.

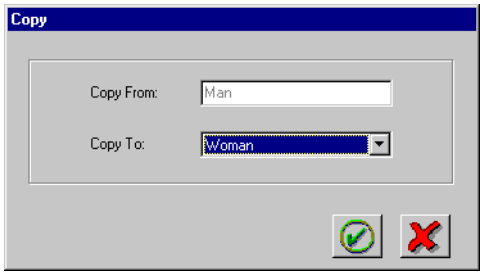
4 Select an empty (available) flagging set or select the next available (empty) row.

5 Highlight the flagging set you want to "Copy From".

For example, to copy from the *Man* flagging set, select *Man*.

Note: You can **Copy From** the Standard flagging set, but you cannot **Copy To** it

6 **Copy**.



7 Select the flagging set that you want to "Copy To".

a. .

b. Highlight the flagging set.

For example, to copy to the *Woman* flagging set, select *Woman* from the list.

8 to copy.

9 Verify that the patient limit ranges have been copied correctly.

Enabling/Disabling RUO (Research Use Only) Parameters

The RUO parameters for this instrument include: PCT, PDW, ATL, and IMM. When USA is the selected country, these parameters are defined as "For Research Use Only. Not for use in diagnostic procedures."

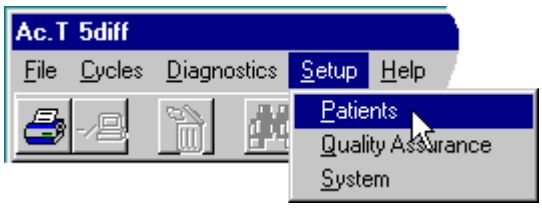
If you want the results for the RUO parameters displayed, printed, and/or transmitted, you must enable the RUO parameter feature as described below.

Note: Whenever an RUO parameter label is displayed, printed, and/or transmitted, the following message will be displayed, printed, and/or transmitted: *"For Research Use Only. Not for use in diagnostic procedures."*

Enabling RUO Parameters

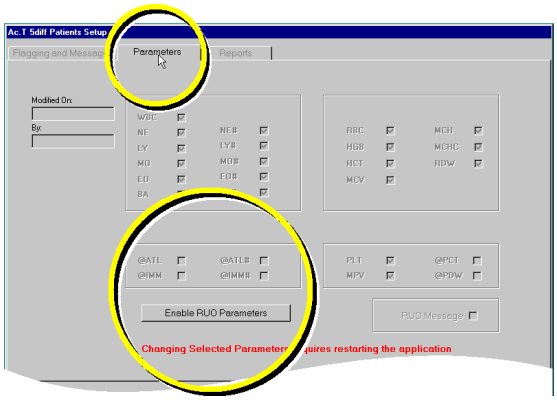
Do this procedure to enable the reporting of the RUO parameters.

1 **Setup** ▸▸ **Patients**.



2 Type the password and .

3 the **Parameters** tab.



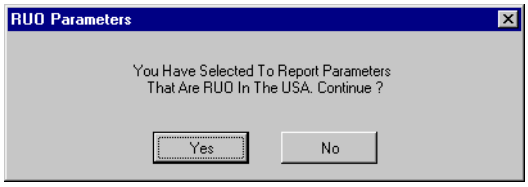
4 **Enable RUO Parameters**.

Note: If **Enable RUO Parameters** is not available, then the RUO parameters are already enabled and you do not have to continue with this procedure.

5 and select one of the following:

- **U.S.A.**
- **Non-U.S.A.**
- **None**

6 **Yes** to confirm that you have selected to report RUO parameters.



ATTENTION: If you selected **U.S.A.**, you must complete the RUO Certification form that automatically prints. Follow the instructions on the form.

7 Verify that the printer is ready.

8 **OK** to confirm that you will be automatically logged out.

9 Wait while the systems logs out.

10 Log in again:

a. When the Begin Logon box appears, simultaneously press Ctrl + Alt + Delete.

b. Type User name `BCI` and press Tab.

c. Type Password `123`.

d. Press Enter or **OK**.

11 Wait for the Analyzer connection to be established.

12 **Setup** ▸▸ **Patients**.

13 Type the password and .

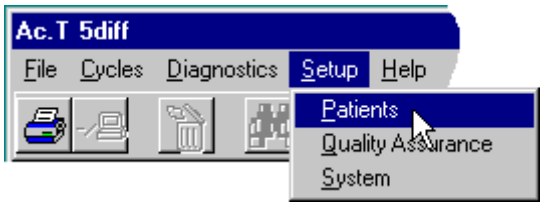
14 the **Parameters** tab.

15 Verify that the RUO parameters are selected.

Disabling RUO Parameters

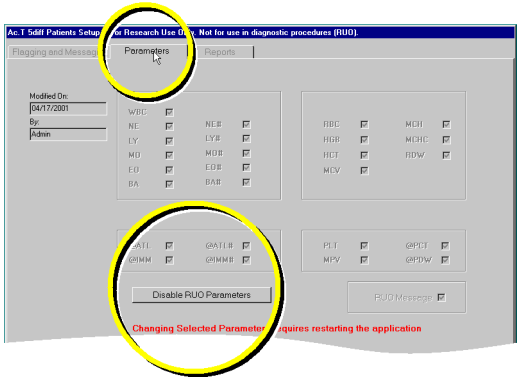
Do this procedure to disable the reporting of the RUO parameters.

1 **Setup** ▸▸ **Patients**.



2 Type the password and .

3 the **Parameters** tab.



4 **Disable RUO Parameters**.

Note: If **Disable RUO Parameters** is not available, then the RUO parameters are already disabled and you do not have to continue with this procedure.

5 **OK** to confirm that you will be automatically logged out.

6 Wait while the systems logs out.

7 Log in again:

a. When the Begin Logon box appears, simultaneously press Ctrl + Alt + Delete.

b. Type User name `BCI` and press Tab.

c. Type Password `123`.

d. Press Enter or **OK**.

8 Wait for the Analyzer connection to be established.

9 **Setup** ▸▸ **Patients**.

10 Type the password and .

11 the **Parameters** tab.

12 Verify that RUO parameters are disabled.

Setting Up the Patient Report

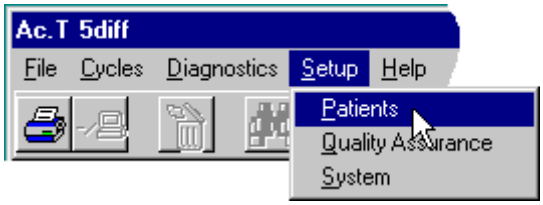
This section contains information about:

- ***Entering a Report Header***
- ***Enabling/Disabling Autoprint for Patient Sample Reports***
- ***Selecting the Number of Copies to Print***
- ***Selecting the Patient Sample Report Printout Option***
- ***Selecting the Patient Sample Report Printout Features***
- ***Selecting the Parameters to Print***

Entering a Report Header

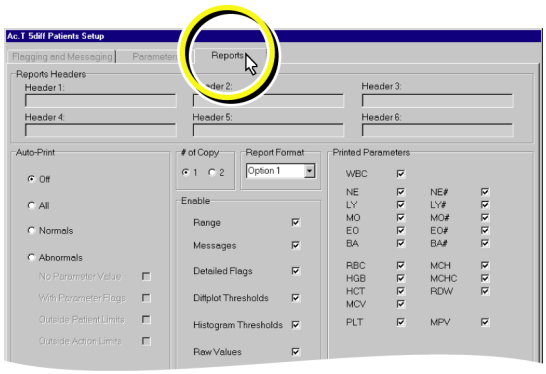
Do this procedure to enter your laboratory's information, such as lab name, address, and so forth, that you want printed on the top of each patient sample report.

1 **Setup** ▸▸ **Patients**.



2 Type the password and .

3 the **Reports** tab.



4 Type your laboratory's information:

a. Type your laboratory's name in the Header 1 field.

Note: You can type up to 25 alphanumeric characters and spaces in each header field

b. Type the remainder of your laboratory's information in the Header 2 through Header 6 fields.

5 Save the changes:

- to save and exit from the window.

OR

- to save and remain at this window to continue setting up the Patient report.

Enabling/Disabling Autoprint for Patient Sample Reports

Do this procedure to enable (activate) or disable (deactivate) the Autoprint feature that automatically prints patient sample reports upon completion of analysis.

The autoprint feature, when selected, allows the system to automatically print reports that you select.

For information on enabling/disabling autoprint for controls, reproducibility, and calibration, see ***Enabling/Disabling Autoprint for Controls, Reproducibility, and Calibration***.

---

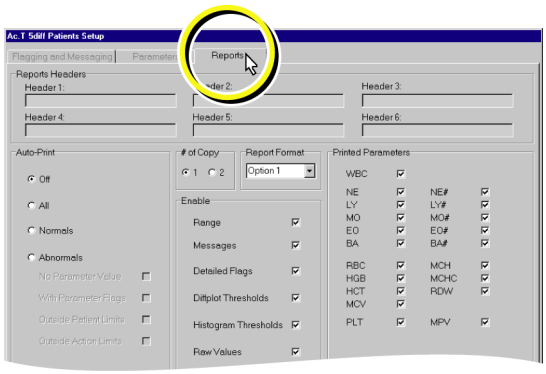
1 **Setup** ▸▸ **Patients**.

---

2 Type the password and .

---

3 the **Reports** tab.

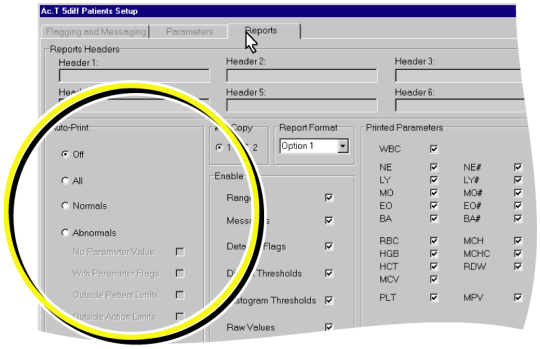


4 the desired option:

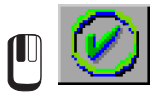
- **Off** (nothing automatically prints)
- **All** (normal and abnormal patient sample results automatically print)
- **Normals** (only normal patient sample results automatically print)
- **Abnormals** (only abnormal patient sample results automatically print)

  If you select **Abnormals**, select one or more of the following options:

  - **No Parameter Value**
  - **With Parameter Flags**
  - **Outside Patient Limits**
  - **Outside Action Limits**



5 Save the changes:

-  to save and exit from the window.

OR

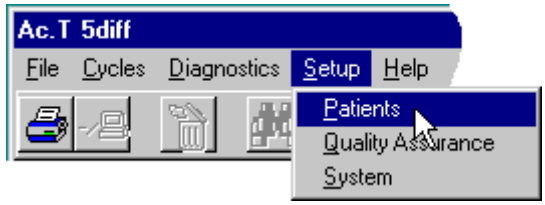
- to save and remain at this window to continue setting up the Patient report.

Selecting the Number of Copies to Print

Do this procedure to define the number of copies (1 or 2) of the patient sample report that you want printed, regardless of whether the reports autoprint.

---

1 **Setup** ▸▸ **Patients**.

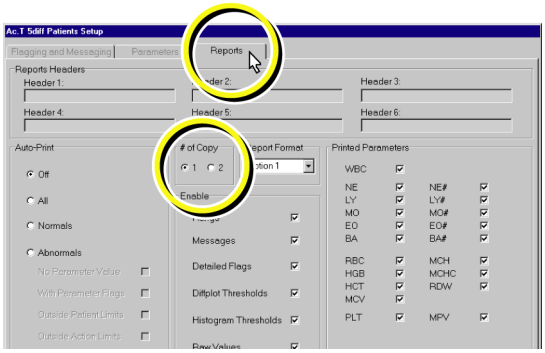


---

2 Type the password and .

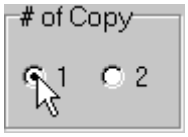
---

3 the **Reports** tab.

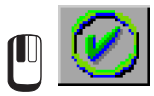


---

4 **1** or **2** for the number of copies to be printed each time.



5 Save the changes:

-  to save and exit from the window.

OR

- to save and remain at this window to continue setting up the Patient report.

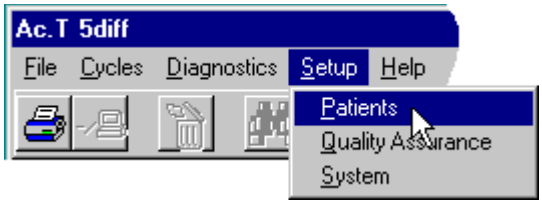
Selecting the Patient Sample Report Printout Option

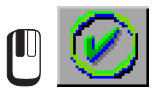
There are three report printing options. The option you choose determines which areas will print on the report (Figure A.2).

- *Option 1* prints report areas 1, 2, and 3.
- *Option 2* prints report areas 1 and 2.
- *Option 3* prints report area 1.

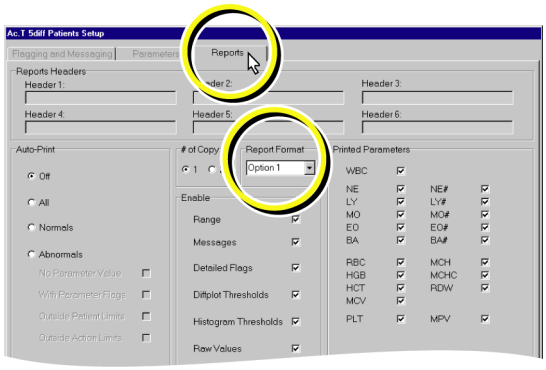
Do this procedure to select the format for the patient sample report printout.

1 **Setup** ▸▸ **Patients**.



2 Type the password and  .

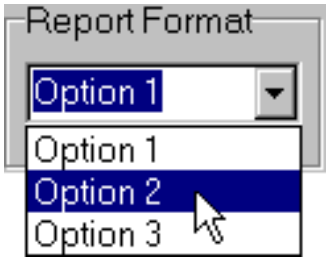
3 the **Reports** tab.



4 Select the desired format option:

a. at the Report Format field.

b. Highlight the desired option.



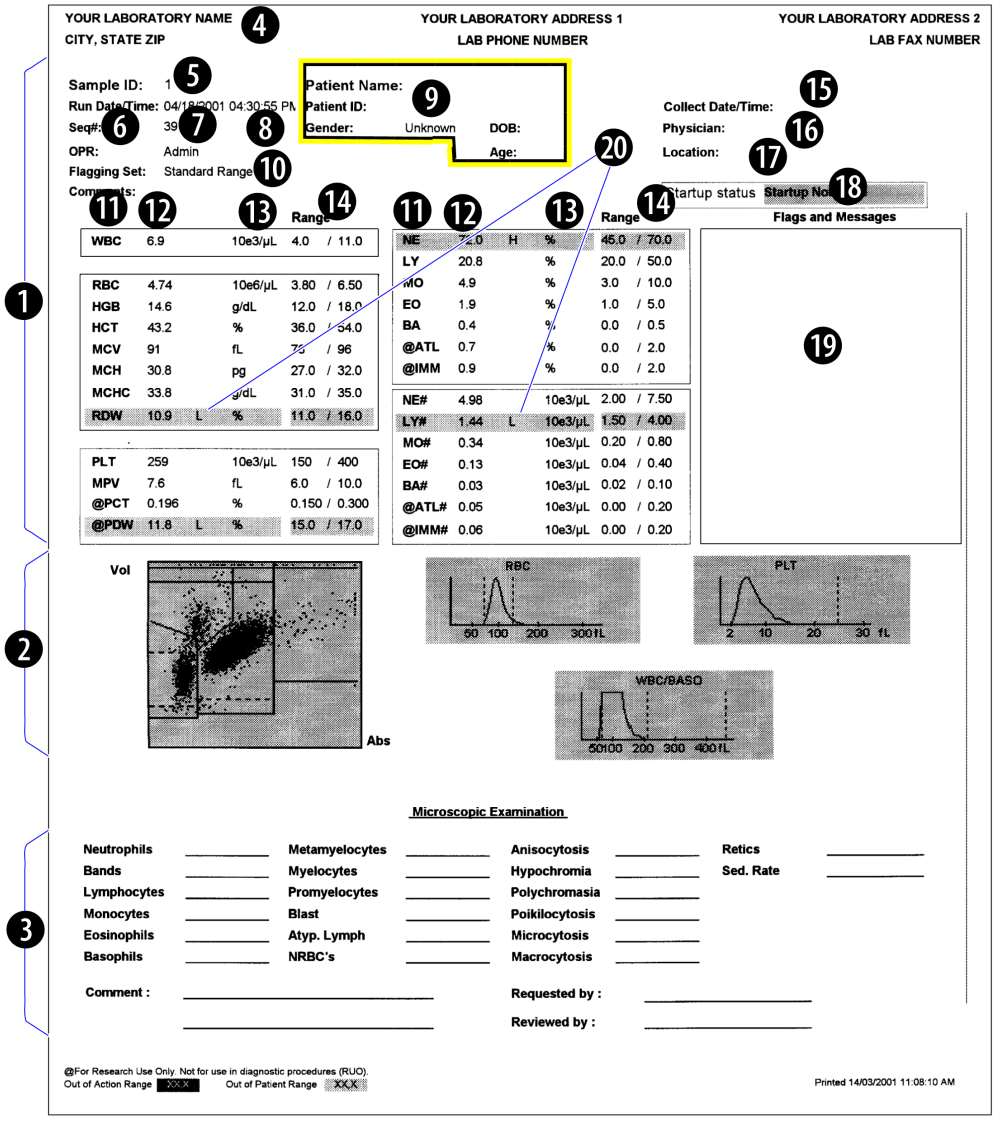
5 Save the changes:

- to save and exit from the window.

OR

- to save and remain at this window to continue setting up the Patient report.

Figure A.2 Sample Results Report: Areas Defined



❶	Area 1 of the report	❽	Time of analysis	⓯	Date/time specimen was collected
❷	Area 2 of the report	❾	Patient information	⓰	Physician
❸	Area 3 of the report	❿	Flagging set	⓱	Location
❹	Header	⓫	Parameter	⓲	Startup status
❺	Sample ID	⓬	Result	⓳	Flags/Messages area for other available flagging information
❻	Sequence number	⓭	Reporting unit	⓴	Flags
❼	Date of analysis	⓮	Range		

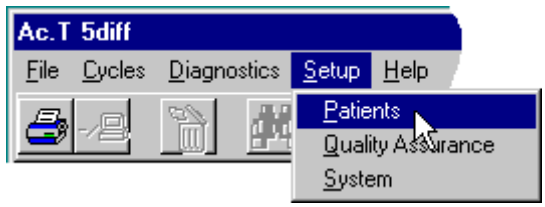
Selecting the Patient Sample Report Printout Features

Do this procedure to select the patient sample report printout features, such as:

- range,
- messages,
- detailed flags,
- diffplot thresholds,
- histogram thresholds, and
- raw values (typically used only for troubleshooting).

---

1 **Setup** ▸▸ **Patients**.

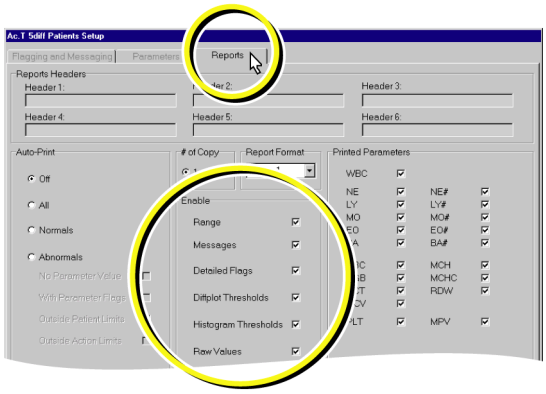


---

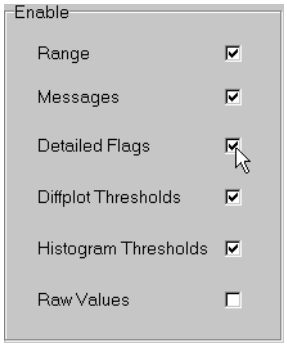
2 Type the password and .

---

3 the **Reports** tab.



4 the box next to the desired features in the Enable field.



5 Save the changes:

- to save and exit from the window.

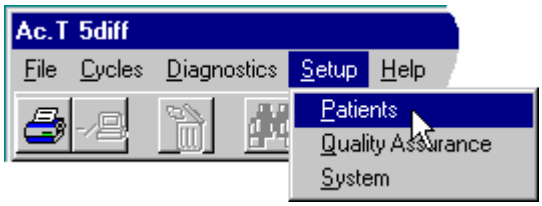
OR

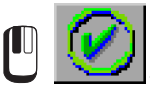
- to save and remain at this window to continue setting up the Patient report.

Selecting the Parameters to Print

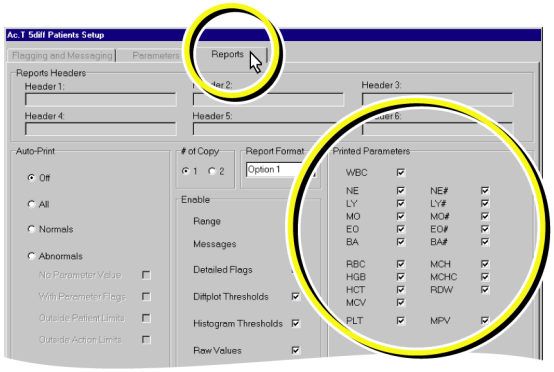
Do this procedure to select which parameters to print.

1 **Setup** ▸▸ **Patients**.

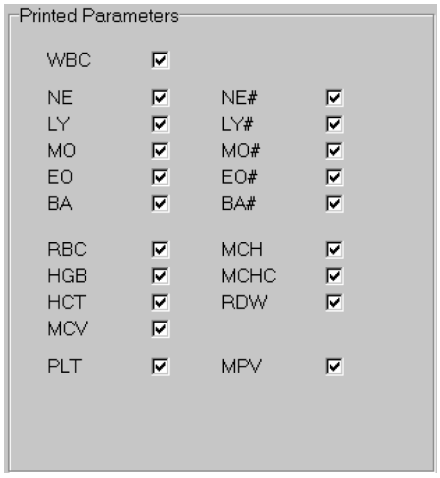


2 Type the password and  .

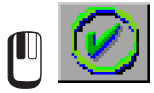
3 the **Reports** tab.



4 the box next to the parameters you want to appear on the printout.



5 Save the changes:

-  to save and exit from the window.

OR

- to save and remain at this window to continue setting up the Patient report.

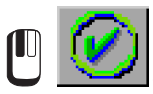
A.5 QUALITY ASSURANCE SETUP

Enabling/Disabling Autoprint for Controls, Reproducibility, and Calibration

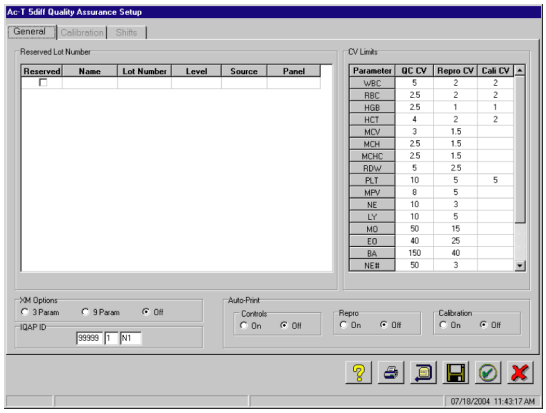
Do this procedure to enable (activate) or disable (deactivate) the Autoprint feature that automatically prints control, reproducibility, and/or calibration reports upon completion of analysis.

For information on enabling/disabling autoprint for patient sample reports, see ***Enabling/Disabling Autoprint for Patient Sample Reports***.

1 **Setup ▸▸ Quality Assurance**.

2 Type the password and  .

3 the **General** tab, if necessary.



4 At the Auto-Print field, the button next to the desired option to enable/disable as needed.

5 to save and exit the window.

Enabling/Disabling XM Options

XM analysis is a method of monitoring your automated hematology analyzer. Similar to XB analysis, XM analysis uses a weighted moving average of patient sample results. You cannot edit or exclude XM values from the current batch or batch details.

XM analysis can be set to monitor either three parameters or nine parameters. Your laboratory must establish its own mean values.

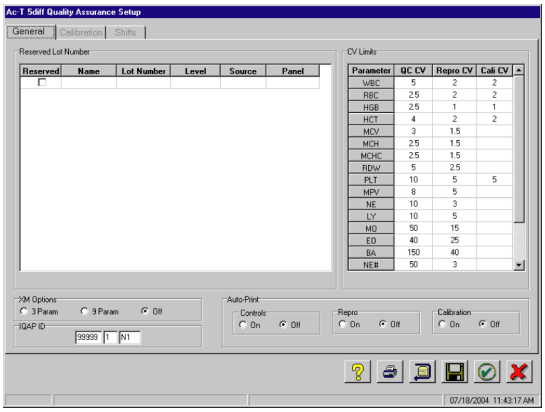
Do this procedure to enable (activate) or disable (deactivate) the XM options:

- **3 Param** (monitors MCV, MCH, and MCHC)
- **9 Param** (monitors WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, and PLT)
- **Off** (default)

1 **Setup** ▸▸ **Quality Assurance**.

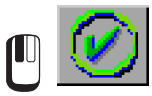
2 Type the password and .

3 the **General** tab, if necessary.



4 At the XM Options field, the button next to the desired option to enable/disable as needed.

5 Save the changes:

-  to save and exit from the window.

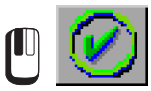
OR

- to save and remain at this window to continue editing.

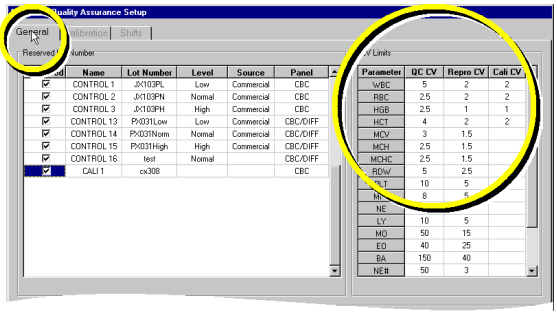
Defining Parameter CV Limits for QC (Quality Control)

Do this procedure to define the CV (coefficient of variation) limits for QC. These are the CV limits that the values in the control files are compared against.

1 **Setup** ▸▸ **Quality Assurance**.

2 Type the password and  .

3 the **General** tab, if necessary.



4 Edit the CV Limits:

a. At the CV Limits area, highlight the number to edit.

b. Edit the number.

c. Repeat steps a and b as needed.

5 Save the changes:

- to save and exit from the window.

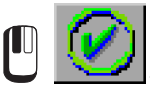
OR

- to save and remain at this window to continue editing.

Defining Shifts

Do this procedure to define your laboratory's shifts to be either a 24-hour shift or multiple shifts.

1 **Setup** ▸▸ **Quality Assurance**.

2 Type the password and  .

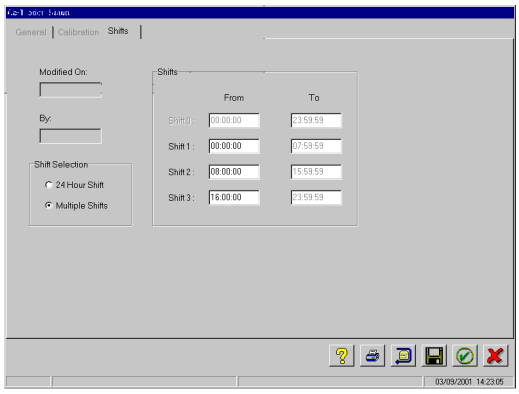
3 the **Shifts** tab,.

4 At the Shift Selection field, select the desired option:

- **24 Hour Shift**
- **Multiple Shifts**

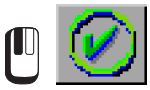
If you selected **24 Hour Shift**, the system defaults are applied, which means no additional shift settings are required. Go to step 6.

If you selected **Multiple Shifts**, go to step 5.



5 For the Multiple Shifts option, type the "From" for each shift.

The "To" is automatically completed when the "From" times are entered. The system automatically prevents the times from overlapping.

6  to save and exit the window.

Setting Up a Control File - Upload from Control Disk

1 the **Quality Assurance** tab.

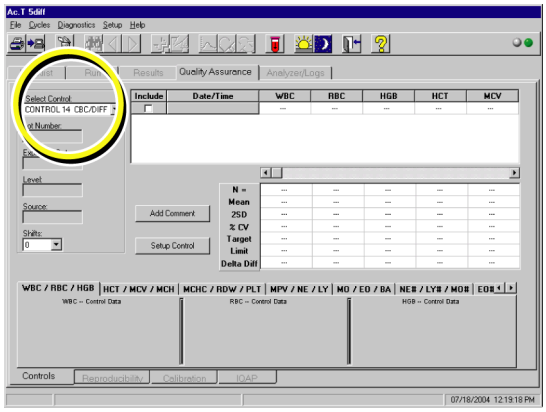
2 the **Controls** tab at the bottom of the window.

3 Select the control to set up:

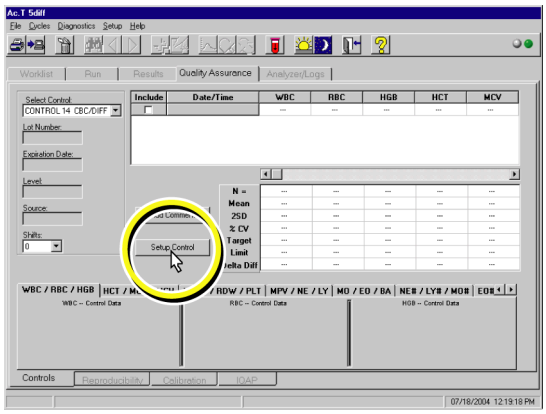
a. At the Select Control field,

.

b. Select the desired control file from the list.

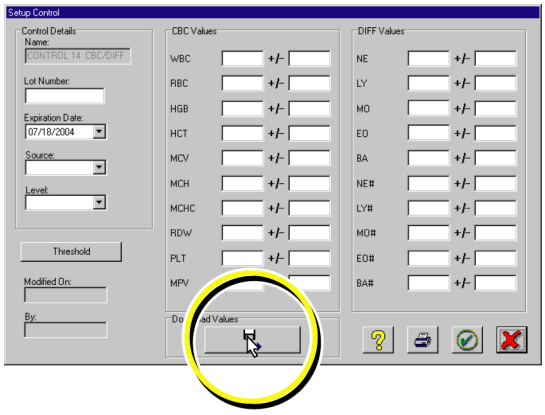


4 **Setup Control**.



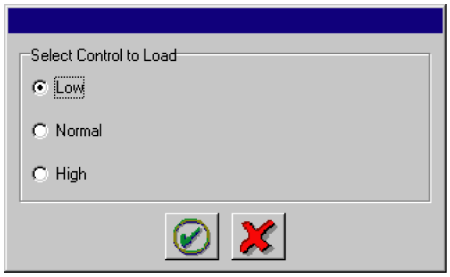
5 Insert the correct assay values diskette into the floppy drive.

6 Select the Download Values button.



7 Select the control level then

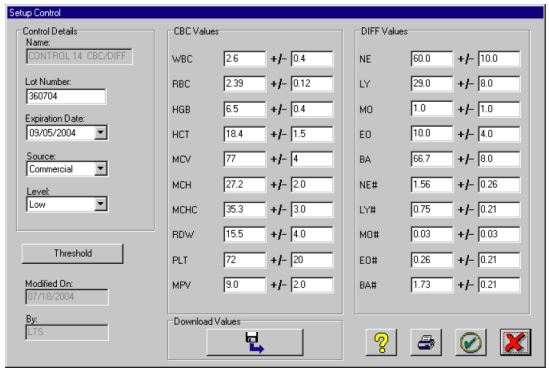
.



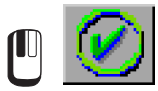
8 Select **Commercial** as the source of the control material if it is not already displayed:

a. at the Source field.

b. Select **Commercial**.



9 to print a copy of the control setup information for your records.

10  to save the control setup and exit the window.

Setting Up a Control File - Manual Method

1 the **Quality Assurance** tab.

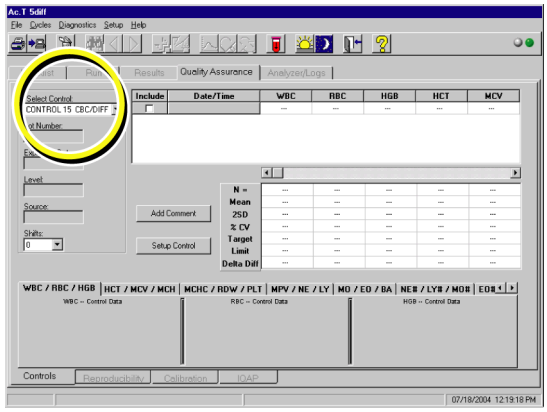
2 the **Controls** tab at the bottom of the window.

3 Select the control to set up:

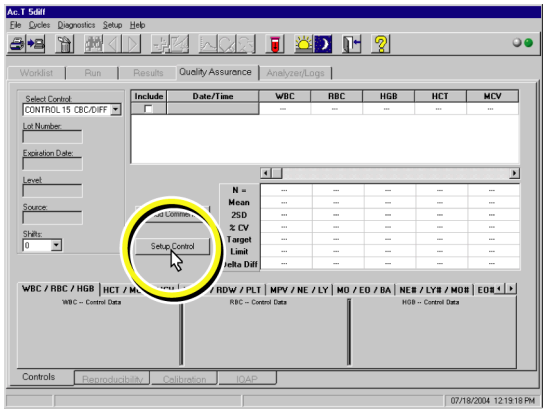
a. At the Select Control field,

.

b. Select the desired control file from the list.


Ac.T 5diff
File Cycles Diagnostics Setup Help
Worklist Run Results Quality Assurance Analyzer/Logs
Select Control:
CONTROL 15 CBC/DIFF
Include Date/Time WBC RBC HGB HCT MCV
Add Comment
Setup Control
N =
Mean
2SD
% CV
Target
Limit
Delta Diff
WBC / RBC / HGB HCT / MCV / MCH MCHC / RDW / PLT MPV / NE / LY MO / EO / BA NE# / LY# / MO# EO#
Controls Reproducibility Calibration IQAP
07/18/2004 12:19:18 PM

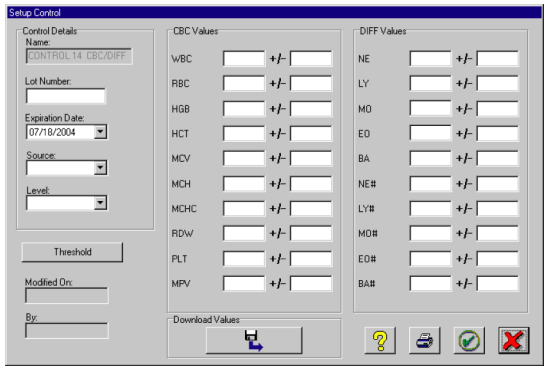
4 **Setup Control**.



5 Enter the lot number of the control material:

a. Locate the lot number on the control material's vial.

b. Enter the lot number (up to 10 alphanumeric characters with no spaces) into the Lot Number field.



6 Press Tab to move to the next field.

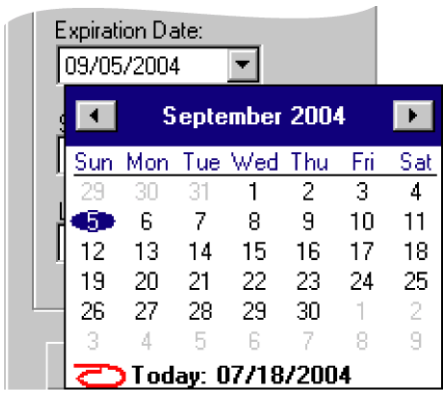
7 Select the control's expiration date:

a. at the Expiration Date field to open the calendar that shows the current date.

b. Select the expiration date:

1) to advance to the correct month.

2) the correct day.



8 Press Tab to move to the next field.

9 Select the source of the control material:

a. at the Source field.

b. Select **Patient** or **Commercial** as the source. (Be sure that the reference values are known for the material you select.)

10 Press Tab to move to the next field.

11 Select the control's level (low, normal, or high):

a. at the Level field.

b. Select the level: **Low**, **Normal**, or **High.**

12 Press Tab to move to the next field.

13 Enter the assigned values and expected ranges from the A^{C}•T 5diff Control Plus control assay sheet for each parameter.

Press Tab to move to the next field after each entry.

14 to print a copy of the control setup information for your records.

15 to save the control setup and exit the window.

Sensitivity and Thresholds

The **Threshold** button on the Setup Control screen displays the Sensitivity and Thresholds for the control. This screen is **for Service use only**. If you accidentally access this screen, select the **Target** button to return to the correct display.

IMPORTANT Do not make any adjustments without first consulting a Beckman Coulter representative. Otherwise, your system may not perform to specifications. Any change to thresholds or sensitivity affect overall system performance.

Reserving Control Lot Numbers

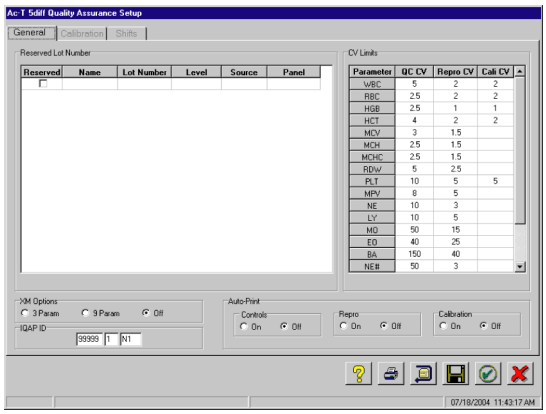
Do this procedure to reserve a lot number for a specific control material. This allows you to enter the lot number as the Sample ID at the Run screen. Based on that, the system will recognize the Sample ID as being a control and will place the control results in the correct control file.

ATTENTION: The control must be set up before the lot number can be reserved.

1 **Setup** ▸▸ **Quality Assurance**.

2 Type the password and .

3 the **General** tab, if necessary.



4 At the Reserved Lot Number field, select the control lot that you want to reserve:

a. the box in the Reserved column that corresponds to the desired control lot.

b. Verify that ☑ appears next to the desired control lot.

5 to save and exit the window.

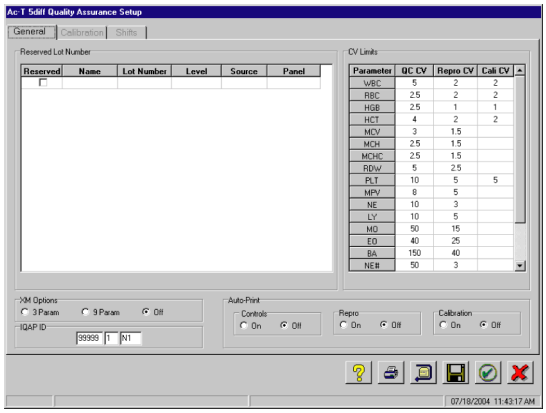
Setting Up the IQAP ID

As soon as you are enrolled in the IQAP program, set up your IQAP ID in the workstation as follows. This must be done before you download control data to disk to submit to IQAP.

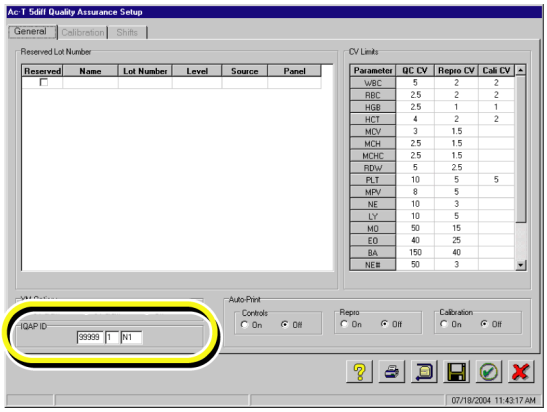
1 **Setup** ▸▸ **Quality Assurance**.

2 Type the password and .

3 the **General** tab, if necessary.



4 At the IQAP ID field, type in your IQAP ID.



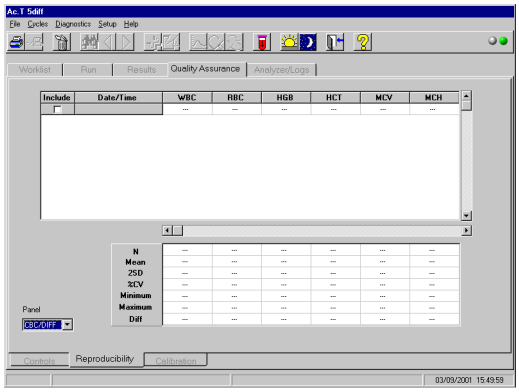
5 to save and exit the window.

Reproducibility Run/Results

Do this procedure to run reproducibility.

1 the **Quality Assurance** tab.

2 the **Reproducibility** tab at the bottom of the window.



3 Select the panel – **CBC** or **CBC/DIFF**:

a. At the Panel field, .

a. Select the desired panel – **CBC** or **CBC/DIFF**.

4 Run reproducibility samples:

IMPORTANT Risk of erroneous results if sample is not properly mixed before analysis. Mix the blood specimen gently and thoroughly before analysis according to the tube manufacturer's recommendations and your laboratory protocol.

a. Prepare and mix fresh, normal whole-blood samples as defined by your laboratory guidelines.

b. Insert the tube/vial into the correct slot of the tube holder.

c. Close the tube holder door; analysis begins.

IMPORTANT Do not log out of the Workstation while the Analyzer is running a cycle. Logging out during an Analyzer cycle will cause problems with the Analyzer/Workstation communication.

d. Remove the tube/vial when the door opens.

IMPORTANT Risk of erroneous results if sample is not properly mixed between analyses. Mix the blood specimen gently and thoroughly before each analysis according to the tube manufacturer's recommendations and your laboratory protocol.

5 Repeat step 4 until a minimum of an n of 10 is achieved.

6 Review the data.

7 Select the results to include in the calculation.

8 to print the reproducibility results.

9 Keep a copy of the printout for your records as required.

B.1 OVERVIEW

Use the information in this appendix to test, troubleshoot, and reprogram your barcode scanner.

IMPORTANT Risk of sample mis-identification if your barcode labels do not meet the specifications stated in this appendix. Use only barcode labels that meet the stated specifications.

Definition

A barcode consists of black lines (bars) and white lines (spaces) called elements.

ATTENTION: Beckman Coulter recommends that you verify each barcode reading to ensure correct sample identification.

B.2 BARCODE LABELS

Symbologies

The A^{C}•T 5diff CP analyzer accepts six barcode symbologies:

- Code 128,
- Code 39,
- Codabar,
- Interleaved 2-of-5,
- EAN 8, and
- EAN 13.

ATTENTION: The scanner uses Code 128 symbology for programming and the $ symbol for entering the programming mode. Therefore, the following Code 128 characters must not be used in any combination of the barcodes used to identify the sample: $, **+, and –.**

B.3 BARCODE SPECIFICATIONS

Barcode labels to be used with the A^{C}•T 5diff CP analyzer must meet the following specifications.

- Maximum number of usable characters in barcode label: 16.
- Minimum % PCS (Print Contrast Signal): 15% at 670 nm.
- Maximum resolution of scanner: 0.1 mm (4 mils).
- Maximum label length: 66 mm (2.6 inches).
- Code 128 barcode labels must meet European Standard EN 799.
- Code 39 barcode labels must meet European Standard EN 800.
- Codabar barcode must meet European Standard EN 798.
- Interleaved 2-of-5 (I 2-of-5) barcode labels must meet European Standard EN 801.
- EAN 8 barcode labels must meet EAN (European Article Numbering) Specifications.
- EAN 13 barcode labels must meet EAN (European Article Numbering) Specifications.

Table B.1 shows default barcode settings for each symbology.

Table B.1 Default Barcode Settings

Setting	Code 128❶	Code 39	Codabar	I 2-of-5	EAN 8	EAN 13
Character Length	1 to 16	1 to 16	3 to 16	11❸	7	12
Check Digit (Checksum)❷	Always Enabled	Enabled	Not Available	Enabled	Always Enabled	Always Enabled
Start/Stop Equality Check	Not Available	Not Available	Enabled	Not Available	Not Available	Not Available
Start/Stop Equality Output	Not Available	Not Available	Disabled	Not Available	Not Available	Not Available

❶ Code 128 provides excellent density, alphanumeric characters, and good security. Recommend using this symbology if using barcodes for the first time, and if compatible with other bar code systems used in your lab.

❷ For increased sample identification integrity, always use Check Digit (Checksum).

❸ Number of characters for I 2-of-5 can be programmed for other lengths, including variable length. However, the variable length is NOT recommended for I 2-of-5 due to the possibility of capturing a partial read of the bar code label.

B.4 BARCODE LABEL TEST PAGES

See Tables B.2 and B.3.

Table B.2 Test Labels With the Check Digit (Checksum)

 Code 128	 EAN 8 Reads 12345670
 Code 39 If this label is read with Check Digit disabled, the last character "$" is also displayed	 EAN 13 Reads 1234567890128
 Interleaved 2-of-5. Reads 11 characters with Check Digit or reads 12 characters without Check Digit.	

Table B.3 Test Labels Without the Check Digit

 Code 39 Label will not read if scanner is programmed to default condition.
 Codabar

B.5 BARCODE SCANNER CONFIGURATION

To restore the barcode scanner to default settings, read each bar code from top to bottom on each column of Table B.4 until all bar codes are read.

Bar codes with S+ and $- will sound multiple beeps when read. Other codes will only sound a single beep.

Table B.4 Barcode Scanner Configuration Sheet

B.6 CODE 39 AND CODABAR BARCODE SCANNER OPTIONS

- For Code 39, see Table B.5, Code 39 Barcode Scanner Options.
- For Codabar, see Table B.6, Codabar Barcode Scanner Options.

Table B.5 Code 39 Barcode Scanner Options

Read ONE of the labels below to set Check Digit control option
Code 39 No Check Digit control
Code 39 Check Digit control

Table B.6 Codabar Barcode Scanner Options

Read ONE of the labels below to set Start/Stop Equality option check
No Start/Stop equality check nor transmission
No Start/Stop equality check but transmission
Start/Stop equality check but no transmission
Start/Stop equality check and transmission

B.7 I 2-OF-5 PROGRAMMING OPTIONS AND TEST LABELS

See Table B.7.

Table B.7 Interleaved 2-of-5 Options With Fixed Length Characters Test Labels

Number of Characters (Check Digit or No Check Digit)	With Check Digit	No Check Digit	Fixed Digit Test Labels
	Read this label first, then ONE of the other labels below	Read this label first, then ONE of the other labels below	
3 or 4			
5 or 6			
7 or 8			
9 or 10			
11 or 12			
13 or 14			

Table B.7 Interleaved 2-of-5 Options With Fixed Length Characters Test Labels *(Continued)*

15 or 16			
3 to 15 or 4 to 15			

Note: Variable Length Characters are NOT recommended for Interleaved 2-of-5 Barcodes. To increase sample identification integrity, use fixed length characters with Check Digit. If the test label fails to read:

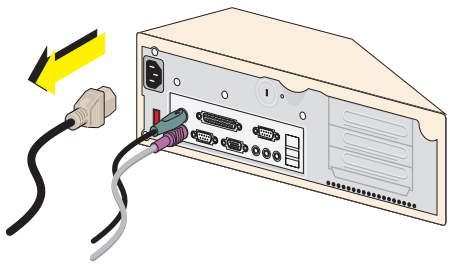
1. Reset the scanner by doing ***Power Down the System*** then ***Power Up the System***.
2. Repeat the programming sequence.

B.8 CONNECTING THE OPTIONAL BARCODE READER

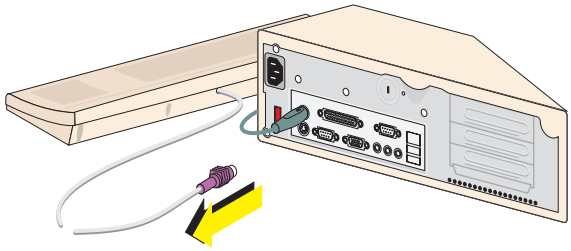
Do this procedure to connect the barcode reader to the Workstation or to verify the connection.

1 Power down the instrument as instructed in ***Power Down the System*** in Chapter 5.

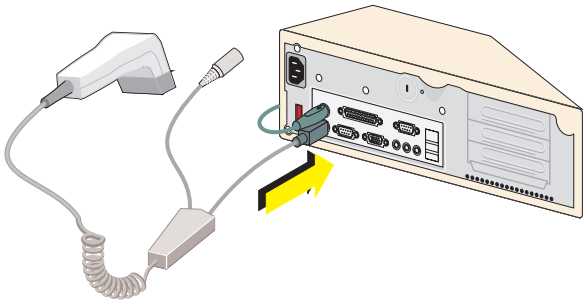
2 Disconnect the Workstation's power cord.



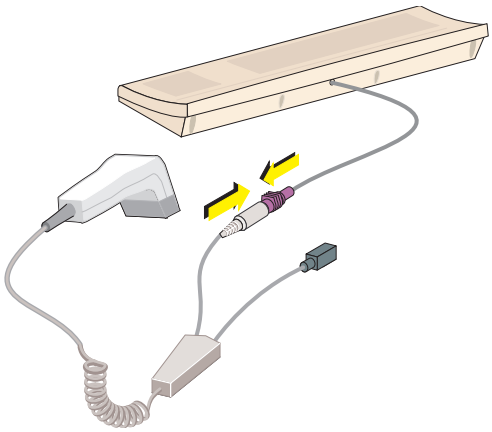
3 Disconnect the keyboard from the Workstation.



4 Connect the barcode reader to where the keyboard was previously connected.



5 Connect the keyboard to the other barcode reader connector.



6 Reconnect the power cord to the Workstation.

7 Power up the system as instructed in ***Power Up the System*** in Chapter 5.

The power on sequence should now perform a startup and background cycle if Auto-Startup is selected.

8 Program the barcode reader to the default configuration as instructed in ***Heading B.5, BARCODE SCANNER CONFIGURATION***.

C.1 ANALYSIS PROCEDURE

Use a material with known reference values as your calibrator.

1 Be sure you have done ***Heading 10.2, PRE-CALIBRATION CHECKS***.

2 Prepare your material as needed.

3 Insert the tube into the tube holder and close the door.

4 Record the results on the calibration worksheet.

CALIBRATION WORKSHEET

Sample Number	WBC	RBC	Hgb	Hct	Plt
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
TOTAL					
MEAN (A)					
ASSIGNED VALUE (B)					
ABSOLUTE DIFFERENCE (C)					
CALIBRATION REQUIRED					
CURRENT CALIBRATION FACTOR (D)					
NEW CALIBRATION FACTOR (E)					

C = B - A
E = (B / A) x D

5 Repeat steps 3 and 4 ten more times, for a total of 11 runs.

6 Do ***Heading C.2, CALCULATIONS PROCEDURE***.

C.2 CALCULATIONS PROCEDURE

1 Calculate the mean for each parameter using samples 2 through 11 on the worksheet. Write this number into row A on the worksheet.

2 Copy your calibrator material's assigned value to the worksheet. Write this number into row B on the worksheet.

3 Calculate the absolute difference between the assigned value and the mean value calculated in step 1. Write this number into row C of the worksheet.

4 Determine if calibration is necessary by comparing the absolute difference from row C to your material's calibration criteria table.

- If the absolute difference is less than the value in your material's calibration criteria table, no calibration is required.
- If the absolute difference is between the values found in your material's calibration criteria table, do ***Heading C.3, CALCULATING NEW CALIBRATION FACTORS***.
- If the absolute difference is greater than the value found in your material's calibration criteria table, eliminate possible instrument problems and possible calibrator deterioration. If you determine calibration may be needed, contact a Beckman Coulter Representative before calibrating.

C.3 CALCULATING NEW CALIBRATION FACTORS

1 Do ***Heading 10.4, MANUAL CALIBRATION FACTOR ADJUSTMENT***.

2 Record these factors into row D on the worksheet.

Calibration Worksheet

Sample Number	WBC	RBC	Hgb	Hct	Plt
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
TOTAL					
MEAN (A)					
ASSIGNED VALUE (B)					
ABSOLUTE DIFFERENCE (C)					
CALIBRATION REQUIRED					
CURRENT CALIBRATION FACTOR (D)					
NEW CALIBRATION FACTOR (E)					

A = samples 2 through 11
C = B - A
E = (B / A) x D

D.1 TUBES APPROVED FOR USE WITH CP SYSTEM

Table D.1 lists tubes shown to be compatible with the cap pierce mechanism of the A^{C}•T 5diff CP system. Beckman Coulter does not recommend the use of one tube in preference to another nor guarantee the acceptability of the sample tube to produce quality results.

If you need information on a tube not listed in this appendix, contact a Beckman Coulter representative.

Note: Tube product numbers change frequently. Verify the tube product numbers with the tube manufacturer.

Table D.1 Specimen Tubes for Use with the Tube Holders

Manufacturer and Tube Name	Product Number	Volume (mL unless otherwise stated)	Size (mm)	Cap Pierceable?	Position in Tube Holder #1	Position in Tube Holder #2	See Note
A^{C}•T 5diff Cal Calibrator	7547175	2.0	13X75	Yes	1	4	–
A^{C}•T 5diff Control Plus	7547198	2.3	13x75	Yes	1	4	3
Becton-Dickinson (BD) Microtainer	365974	0.25 to 0.50	–	No	4	–	–
BD Microtainer	365973	0.25 to 0.50	–	No	–	1	–
BD Hemogard (glass) K3	369651	2	13x75	Yes	1	–	1, 2
BD Hemogard (glass) K3	367661	3	13x75	Yes	1	–	1, 2
BD Hemogard (glass) K3	367650	3	13x75	Yes	1	–	1, 2
BD Hemogard (glass) K3	367652	3	13x75	Yes	1	–	1, 2
BD Hemogard (glass) K3	367653	5	13x75	Yes	1	–	1, 2
BD Hemogard (glass) K3	367658	5	13x75	Yes	1	–	1, 2
BD Hemogard (glass) K3	367662	5	13x75	Yes	1	–	1, 2
BD Hemogard (plastic) K2	367841	2	13x75	Yes	1	–	1, 2
BD Hemogard (plastic) K2	367842	2	13x75	Yes	1	–	1, 2
BD Hemogard (plastic) K2	367856	3	13x75	Yes	1	–	1, 2
BD Hemogard (plastic) K2	367859	3	13x75	Yes	1	–	1, 2
BD Hemogard (plastic) K2	367861	4	13x75	Yes	1	–	1, 2
BD Hemogard (plastic) K2	367862	4	13x75	Yes	1	–	1, 2

Table D.1 Specimen Tubes for Use with the Tube Holders

Manufacturer and Tube Name	Product Number	Volume (mL unless otherwise stated)	Size (mm)	Cap Pierceable?	Position in Tube Holder #1	Position in Tube Holder #2	See Note
BD Vacutainer (glass) K3	366385	3	10.25x64	Yes	–	2	1
BD Vacutainer (glass) K3	366405	2.5	13x75	Yes	1	–	1, 2
BD Vacutainer (glass) K3	366564	2.5	13x75	Yes	1	–	1, 2
BD Vacutainer (glass) K3	366452	5	13x75	Yes	1	–	1, 2
BD Vacutainer (glass) K3	366536	5	13x75	Yes	1	–	1, 2
BD Vacutainer (plastic) K2	367843	2	13x75	Yes	1	–	1, 2
BD Vacutainer (plastic) K2	367835	3	13x75	Yes	1	–	1, 2
BD Vacutainer (plastic) K2	367844	4	13x75	Yes	1	–	1, 2
Greiner VACUETTE	454087	2	13x75	Yes	1	–	1, 2
Greiner VACUETTE	454086	3	13x75	Yes	1	–	1, 2
Greiner VACUETTE	454041	3	13x75	Yes	1	–	1, 2
Greiner VACUETTE	454036	4	13x75	Yes	1	–	1, 2
Kabe Kabevette® N	070132	3	11.5x65	No	3	–	6
Kabe Kabevette® G	102325	3.5	12.5x76	Yes	1	4	1, 5, 6
Kabe Primavette® V	0959 0510	2.6	11.5x66	Yes	3	–	1, 6
LIP	133017	1	12x42	No	3	–	4
RAM Scientific	07 6011	125 µL	–	No	–	3	–
Sarstedt Monovette	04.1901.200	2.6	13x65	Yes	–	4	1, 5, 6
Sarstedt Monovette	05.1167.100	2.7	11.5x66	Yes	3	–	1, 5, 6
SEIKSU INSE-PACK	SP-0402EM	2	12.6x75	Yes	1	–	1, 2
Terumo Venoject	VT-030STK	3	10.4x65	Yes	–	2	1

Notes:

The minimum sample volume in a collection device is 1 mL for collection devices that have a fill volume greater than 1 mL, and three-quarters the fill volume for collection devices that have a fill volume less than or equal to 1 mL.

1. If the tube is pierceable, it is recommended that the tube not be pierced more than 3 times (except for BD tubes which can be pierced a maximum of 7 times).
2. The tube may also be used in Tube Holder #2, position 4, if it has too many labels to fit in Tube Holder #1.
3. Control material may be pierced until the open vial expiration dating and maximum number of events have been reached.
4. When used, cannot be used with other tubes assigned to this position due to different probe depth adjustments.
5. Due to the aspiration plunger, a different probe depth adjustment is required when used with other tubes in the same position.
6. Prior to cycling, ensure that aspiration plunger is all the way at the bottom of the tube.

E.1 ARCHIVE MANAGEMENT

Archiving is a process used to manage the information stored in the database. The system will use the current active archive as a source for duplicate Sample ID checks. This allows Sample IDs to be reused when a new archive is created.

When you close an archive, it is stored within the database. The filename assigned to the archive is the actual date and time that the archive was created. Multiple archives can be stored in the database.

This section describes how to manage system archives, including creating and opening. It also provides a procedure to print Worklist orders from a previous archive. (**Note**: There is no procedure for saving archives because an archive is automatically saved when a new one is created.)

See Table 2.9 for additional information.

Creating an Archive

IMPORTANT Risk of compromising system functionality if archives are not performed at the recommended intervals. Beckman Coulter recommends that the archive function be performed a minimum of once a month.

Do this procedure to create a new archive. When you create a new archive, your current active archive is automatically saved.

To determine when to create a new archive, see Table 2.9.

---

1 If you were reviewing an old archive,

File ▸▸ Close archive.

Note: You cannot create a new archive until any previously opened archive, if any, is closed.

---

2 **File ▸▸ New archive**.

---

3 Resume normal operation using the new archive, which is now your current active archive.

Opening a Saved Archive

Do this procedure to open a saved archive.

---

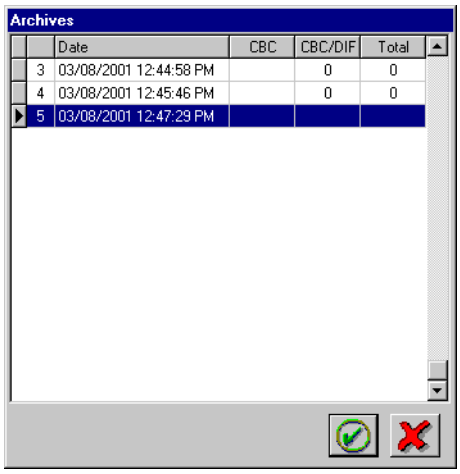
1 **File** ▸▸ **Open archive**.

---

2 Highlight the archive to open from the list and .

Note: The Worklist and results list for an old archive will be colored light green. If an old archive has Worklist entries without results (never analyzed), the entries will be displayed in white.

(The current active archive background is white, and in this view no statistics appear for the active archive.)



Printing a Worklist from a Previous Archive

Do this procedure to print Worklist orders that are not in the current active archive.

---

1 Open the archive where the Worklist orders are located:

a. **File** ▸▸ **Open archive**. (The date displayed indicates when the archive was created.)

b. Select the correct archive to open.

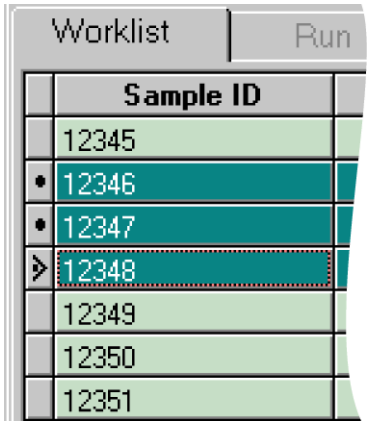
c. .

2 the **Worklist** tab.

3 Select each order you want to print:

a. Press the Ctrl key and on each order you want to print.

b. Verify that a black dot appears in the far left column of the selected order(s) and that the entire row is highlighted.



4 to display the print menu.

5 Select the desired print format:

- To print one or more selected rows, **Print Selected Rows**.
- To print all orders, **Print All Rows**.

E.2 DATABASE MANAGEMENT

A database stores all archives. If the database has been backed up, you can restore patient information from the backup.

This section describes how to manage your database, including backing up, restoring, and deleting. It also describes when and why the system compacts the database.

Backing Up the Database

Do this procedure if you want to make a backup copy of your patient database and save it to the Workstation's hard drive. The default directory is D:\Backup.

Note: A password is required.

---

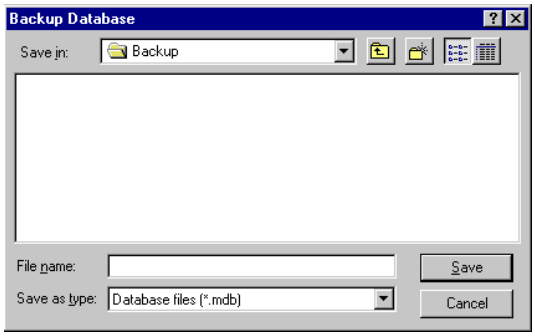
1 **File** ▸▸ **Backup database**.

---

2 Type the password and .

---

3 Enter a file name, such as the current date, using standard file naming conventions.



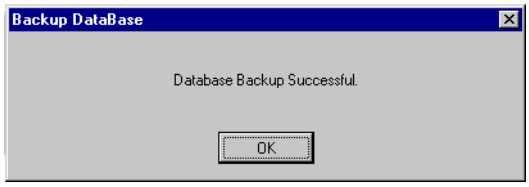
---

4 **SAVE**.

The file extension .MDB is automatically applied to the filename.

5 **OK**.

A backup copy of the database has been saved to the file you named above.



If the database could not be backed up, an error message will appear.

Restoring a Database

Do this procedure if you want to restore a database from a backup copy previously saved to the Workstation's hard drive. The default directory is D:\Backup.

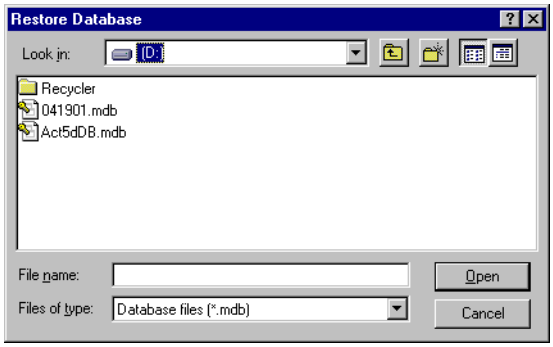
Note: A password is required.

WARNING Current data is deleted when a backed up database is restored.

1 **File** ▸▸ **Restore database**.

2 Type the password and .

3 Locate and highlight the database you want to restore to the hard drive.



4 **Open**.

5 **OK** to log out.

6 Log in again to the Workstation and resume normal operation.

Deleting a Database

Do this procedure if you want to delete the existing database from the Workstation's hard drive.

ATTENTION: You cannot recover a deleted database

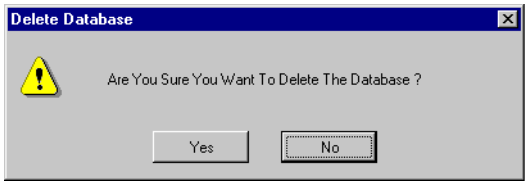
1 Backup the database before deleting it. See ***Backing Up the Database*** for details.

2 **File** ▸▸ **Delete database**.

3 Type the password and .

4 **YES** to confirm that you want to delete the database.

The database is deleted.



5 **OK** to log out.

6 Log in again to the Workstation and resume normal operation.

Database Compacting

The database can store 10,000 results. To optimize performance, the system compacts the database each time you log in.

After 10,000 results have been stored, at the next login, the system automatically deletes the oldest results to reduce the database to 9,500 and allow additional results to be saved.

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4. NCCLS document H4-A3. Procedures for the collection of diagnostic blood specimens by skin puncture. National Committee for Clinical Laboratory Standards. Villanova, PA, 1991.
5. NCCLS document H3-A3. Procedures for the collection of diagnostic blood specimens by venipuncture. National Committee for Clinical Laboratory Standards. Villanova, PA, 1991.

DEFINITIONS

accuracy	Ability of the instrument to agree with a predetermined reference value at any point within the operating range; closeness of a result to the true (accepted) value.
agglutination	clump
background count	Measure of the amount of electrical or particle interference.
blank cycle	Runs diluent through the system to clean it out.
calibration	A procedure to standardize the instrument by determining its deviation from calibration references and applying any necessary correction factors.
calibration factors	These are correction factors that the system uses to fine-tune instrument accuracy.
calibrator	A substance traceable to a reference method for preparation or material used to calibrate, graduate, or adjust measurement.
carryover	The amount, in percent, of blood cells of Hgb remaining in diluent following the cycling of a blood sample.
cell control	A preparation made of human blood with stabilized cells and surrogate material used for daily instrument quality control.
characteristics	*See* performance characteristics.
coefficient of variation	An expression in percent of data (SD) spread related to the mean. CV% = (SD/mean)x100
control	A substance used for monitoring the performance of an analytical process or instrument.
conventions	A standard style or format used in a manual.
CV	*See* coefficient of variation.
default	An original, factory-setting.
expiration date	The last day that you can use that specific lot number of reagent, control, or calibrator.
fL	Abbreviation for femtoliter.
femtoliter	One quadrillionth (10^{15}) of a liter.
field	An area on a screen for entering data.
flags	On printouts, letters or symbols that appear next to parameter results to indicate specific conditions. For additional information, see ***Heading 9.3, REVIEWING FLAGGED RESULTS***.
LIS (laboratory information system)	A laboratory's computer system that stores patient information and analysis results.
linearity	The ability of an instrument to recover expected results (reference values or calculated values) for such parameters as WBC, RBC, Hgb, and Plt, at varying levels of concentration of these parameters within specified limits.
lot number	A manufacturer's code that identifies when the product, such as a reagent, was manufactured.
mean	Arithmetic average of a group of data.
mode	The analysis, either CBC or CBC/DIFF, performed by the instrument.
operating range	Range of results over which the instrument displays, prints, and transmits data.

panel	Specifies the group of tests – CBC or CBC/DIFF – ordered for the patient.
parameter	A component of blood that the instrument measures and reports.
performance characteristics	Actual performance of the instrument.
performance specifications	Targeted performance of the instrument based on established ranges and parameters.
precision	A measure of reproducibility, precision is the ability of the instrument to reproduce similar results when a sample is repeatedly run. Precision of the instrument is a CV%, or an SD for DIFF parameters, based on replicate determinations of the same sample. Precision shows the closeness of test results when repeated analyses of the same material are performed.
primary window	The main window displayed when the application begins. *See* secondary window.
quality control (QC)	A comprehensive set of procedures a laboratory establishes to ensure that the instrument is working accurately and precisely.
reportable range	The lowest to highest concentration that can be reported without dilution or other modifications to the sample.
reproducibility	This procedure checks that the system gives similar results (within established limits) every time it measures the same sample. *Also called* precision.
secondary window	Any window displayed over the primary window when a secondary function is requested. *See* primary window.
SD (standard deviation)	A measure of variation within a group of samples or within a population.
shutdown cycle	Cleans the instrument's fluidic lines and apertures to help prevent residue buildup.
specifications	*See* performance specifications.
startup cycle	Ensures that the instrument is ready to run; includes performing a background test.
stat	*See* statim.
statim[3]	At once or immediately. Commonly referred to as "stat".
TABLE OF EXPECTED RESULTS	Assigned values for a control material used for quality control parameters. Usually reported on package insert shipped with the control material; can be a separate assay sheet.
verification	Procedure to analyze cell controls or whole blood with known values to determine if your results are within expected range.
whole blood	Non-diluted blood; blood and anticoagulant only.
workstation	The personal computer and software used for data analysis and results storage.
XB (X bar B)	A method of quality control based on the stability of the RBC indices in a patient population.
XM	A group of quality control methods used on a patient population.

LIST OF ABBREVIATIONS

µL	microliter
ACD	acid-citrate-dextrose
ANSI	American National Standards Institute
ASTM	American Society for Testing and Materials
BA	basophil
bps	bits per second
CBC	complete blood count
cm	centimeter
CV	coefficient of variation
DIFF	differential
dL	deciliter
EDTA	ethylenediaminetetraacetic acid
EO	eosinophil
fL	femtoliter
ft	foot or feet
g	gram
gal	gallon
GR	granulocyte
Hct	hematocrit
Hgb	hemoglobin
Hz	hertz
L	liter
LCD	liquid crystal display
LED	light-emitting diode
LIS	laboratory information system
LY	lymphocyte
m	meter
MCH	mean corpuscular hemoglobin
MCHC	mean corpuscular hemoglobin concentration
MCV	mean corpuscular volume
mL	milliliter
mm	millimeter
MO	monocyte
MPV	mean platelet volume
MSDS	material safety data sheet
mW	milliwat

n	number
NCCLS	National Committee for Clinical Laboratory Standards
NE	neutrophil
nm	nanometer
pg	picogram
Plt	platelet
RBC	red blood cell
RDW	red cell distribution width
RUO	Research Use Only
SD	standard deviation
Vac	volts of alternating current
Vdc	volts of direct current
WBC	white blood cell

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A^C•T 5diff Control Plus. *See* cell controls
A^C•T 5diff Diluent
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    See reagents
A^C•T 5diff Fix
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A^C•T 5diff Hgb Lyse
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A^C•T 5diff Rinse
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- **Host Transmission Specification**
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